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# BMJ Open

## An interview study of the experiences of cellulitis diagnosis amongst health care professionals.

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5 2 professionals.

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7 3 **Running head:** Cellulitis diagnosis by health care professionals

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27 Nottingham, UK

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45 26 [https://www.nottingham.ac.uk/research/groups/cebd/documents/researchdocs/protocol-](https://www.nottingham.ac.uk/research/groups/cebd/documents/researchdocs/protocol-diagnosing-lower-limb-cellulitis-health-care-professionals.pdf)  
46 27 [diagnosing-lower-limb-cellulitis-health-care-professionals.pdf](https://www.nottingham.ac.uk/research/groups/cebd/documents/researchdocs/protocol-diagnosing-lower-limb-cellulitis-health-care-professionals.pdf)

## Abstract

**Objectives:** To explore health care professionals (HCPs) experiences and challenges in diagnosing suspected lower limb cellulitis.

**Setting:** UK nationwide.

**Participants:** 20 qualified HCPs, who had a minimum of two years clinical experience as a HCP in the national health service and had managed a clinical case of suspected cellulitis of the lower limb in the UK.

HCPs were recruited from departments of dermatology (including a specialist cellulitis clinic), general practice, tissue viability, lymphoedema services, general surgery, emergency care and acute medicine.

Purposive sampling was employed to ensure that participants included consultant doctors, trainee doctors and nurses across the specialties listed above. Participants were recruited through: national networks,

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3 54 HCPs who contributed to the cellulitis priority setting partnership (PSP), UK Dermatology Clinical Trials  
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6 55 Network, snowball sampling where participants helped recruit other participants, personal networks of the  
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9 56 authors.

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13 57 **Primary and secondary outcomes:** Primary outcome was to describe the key clinical features which inform  
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15  
16 58 the diagnosis of lower limb cellulitis. Secondary outcome was to explore the difficulties in making a  
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19 59 diagnosis of lower limb cellulitis

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22 60 **Results:** The presentation of lower limb cellulitis changes as the episode runs its course. Therefore, different  
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25 61 specialties see clinical features at varying stages of cellulitis. Clinical experience is essential to being  
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28 62 confident in making a diagnosis, but even amongst experienced HCPs, there were differences in the clinical  
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31 63 rationale of diagnosis. A group of core clinical features were suggested, many of which overlapped with  
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34 64 alternative diagnoses. This emphasises how the diagnosis is challenging, with objective aids and a greater  
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36  
37 65 understanding of the mimics of cellulitis required.

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40 66 **Conclusion:** Cellulitis is a complex diagnosis and has a variable clinical presentation at different stages.  
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43 67 Although cellulitis is a common diagnosis to make, HCPs need to be mindful of alternative diagnoses.

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47 68 **Keywords:** lower limb, cellulitis, diagnosis, health care professionals  
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54 70 **Article summary**

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3 71 Strengths and limitations of this study  
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- 7 72 • Two independent coders following a standardized codebook.  
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10 73 • Participants were included nationally around the UK, across various specialities that  
11  
12 commonly diagnose cellulitis, with both nurses and doctors of varying clinical experience.  
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14 74  
15  
16 75 • Some participants were unable to fully describe their clinical rationale behind diagnostic  
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18 decisions during the interview.  
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20 76  
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22 77 • Interviewees may not have fully shared the details of cases that were misdiagnosed or  
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24 where diagnoses were delayed due to social desirability bias or fear of litigation.  
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25 90 **Introduction**

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29 91 Cellulitis is a frequent presentation in both the community and secondary care, with 60% of  
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32 92 presentations affecting the lower limbs.<sup>1</sup> However, the diagnosis of cellulitis can be challenging,  
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35 93 with up to a third of suspected lower limb cellulitis cases being later diagnosed as other  
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38 94 diagnoses.<sup>2</sup> This is further compounded by the lack of validated diagnostic criteria or tools for  
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41 95 cellulitis.<sup>3</sup>

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45 96 A UK cellulitis research priority setting partnership (PSP) determined that improving health care  
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48 97 professionals' (HCPs) diagnostic accuracy is a key priority for future cellulitis research.<sup>4</sup> An  
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51 98 interview study of people with recurrent cellulitis and lymphoedema suggested that patients often  
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3 99 experience difficulties in obtaining a speedy and accurate diagnosis (accepted by British Journal  
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6 100 of General Practice).  
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10 101 The aims of this interview study was to explore the HCP experiences and challenges faced in  
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13 102 diagnosing suspected lower limb cellulitis.  
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51 111 **Methods**

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55 112 **Protocol registration and Ethics**  
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3 113 The final protocol was registered on the Centre of Evidence Based Dermatology (CEBD) website  
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7 114 (9 May 2019). Ethical approval was granted by the Health Research Authority and Health and  
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10 115 Care Research Wales (19/HRA/0485) (30 November 2018). Verbal and written consent was  
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12  
13 116 obtained from each participant.  
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### 17 117 **Patient and public involvement**

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21 118 The research question was developed from research priorities in the cellulitis PSP, involving  
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24 119 patients. A patient representative helped design this study and is a co-author. On publication,  
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27 120 participants will be sent the final manuscript.  
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### 31 121 **Eligibility criteria**

### 35 122 **Selection of participants**

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39 123 Participants were qualified HCPs, who had a minimum of two years clinical experience as a HCP  
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42 124 in the national health service (NHS) and had managed a clinical case of suspected cellulitis of the  
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45 125 lower limb in the UK. HCPs were recruited from departments of dermatology (including a specialist  
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48 126 cellulitis clinic), general practice, tissue viability, lymphoedema services, general surgery,  
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51 127 emergency care and acute medicine.  
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3 128 Purposive sampling was employed to ensure that participants included consultant doctors, trainee

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6 129 doctors and nurses across the specialties listed above. Participants were recruited through:

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10 130 • National networks

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13 131 • HCPs who contributed to the cellulitis PSP

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15 132 • UK Dermatology Clinical Trials Network

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18 133 • Snowball sampling where participants helped recruit other participants

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22 134 • Personal networks of the authors

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25 135 Data collection and analysis were undertaken concurrently and sampling ceased when thematic

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28 136 saturation had been achieved (i.e. new interviews generated no new insights).

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31 137 **Researcher characteristics**

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34 138 Interviews were conducted by MP, and coded and analysed by MP and SIL (both general

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37 139 practitioner (GP) trainees). The broader research group included experienced clinical-academics

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40 140 (JK and NL), a patient representative (PS), and qualitative experts (JK and PL).

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44 141 **Interview setting**

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47 142 Each participant took part in a single, semi-structured, qualitative interview. These were either

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50 143 face-to-face or via telephone, according to participant preference. All participants received a £20

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54 144 reimbursement voucher or donated this fee to the British Skin Foundation charity.

## 145 **Data collection**

146 Prior to the interview, participants were asked to reflect upon their most recent experiences of  
147 making a cellulitis diagnosis, focusing on the typical presentations, challenging cases and  
148 differential diagnoses.

149 A topic guide, informed by a prior systematic review and interview study,<sup>5</sup> was used to structure  
150 the interview (Supplementary materials, Figure 1). However, participants were urged to propose  
151 and/or expand on topics which they felt were relevant to their experience of diagnosis.

## 152 **Data processing**

153 Interviews were audio-recorded and transcribed. Transcripts were checked (by MP) and data  
154 managed using QSR NVivo 12 software.

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## 156 **Data analysis**

157 Analysis was inductive, searching for themes in the data. A structured, systematic, multi-stage  
158 approach to thematic analysis was followed.<sup>6</sup>

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4 159 Data were coded independently by MP, with SIL also independently coding a third of the  
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7 160 transcripts. Uncertainties in coding and thematic organisation were resolved in discussion with  
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9  
10 161 the other authors. Data collection and analysis was concurrent. The final codebook was agreed  
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13 162 by all authors and is presented in Figure 1.  
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## 174 Results

175 Twenty HCPs were interviewed (Table 1). Interviews were conducted between 19 March and 11  
 24 June 2019.

177 **Table 1: Characteristics of the participants**

Characteristics	Number of participants, n
<b>Gender</b>	
Female	15
Male	5
<b>Age</b>	
25-34	4
35-44	8
45+	7
<b>Ethnicity</b>	
White	13
Asian	5
Black	1

Mixed	1
<b>Specialty and clinical role</b>	
Dermatology	5
Consultant/Trainee/Nurse	3*/1/1
General practice	6
GP/Trainee/Advanced Nurse Practitioner	4** (one locum)/1/1
Emergency care consultants	2
Acute medicine consultants	2
Infectious disease consultant	1***
Lymphoedema nurse	1
General Surgery trainee	1****
Tissue Viability nurse	1
District nurse	1
*One subspecialises in lymphoedema   ** One subspecialises in dermatology *** Also works in acute medicine **** Also worked as an emergency care locum	
<b>Years of clinical experience</b>	
<10	6
11-20	9
20+	5
<b>Number of times the HCP diagnosed lower limb cellulitis</b>	
11-50	6 (30)
50+	14 (70)
<b>Time since the HCP last made a diagnosis of cellulitis</b>	
<1 month	16
1-6 months	3
6+ months	1

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4 179 **Main findings**

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8 180 Four key themes were identified: 1) The patient presentation; 2) Challenges leading to diagnostic  
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11 181 uncertainty; 3) Strategies to improve diagnosis; 4) The need for an objective diagnostic aid, with  
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14 182 further classification into sub-themes. How the codes mapped onto the overarching themes are  
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17 183 shown in Table 2.

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20 184 **Table 2: Characteristics of the participants**

Characteristics	Number of participants, n
<b>Gender</b>	
Female	15
Male	5
<b>Age</b>	
25-34	4
35-44	8
45+	7
<b>Ethnicity</b>	
White	13
Asian	5
Black	1
Mixed	1
<b>Specialty and clinical role</b>	
Dermatology	5
Consultant/Trainee/Nurse	3*/1/1
General practice	6



GP/Trainee/Advanced Nurse Practitioner	4** (one locum)/1/1
Emergency care consultants	2
Acute medicine consultants	2
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Lymphoedema nurse	1
General Surgery trainee	1****
Tissue Viability nurse	1
District nurse	1
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<b>Time since the HCP last made a diagnosis of cellulitis</b>	
<1 month	16
1-6 months	3
6+ months	1

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186 **The patient presentation**187 *The continuum of clinical features*

188 The presentation of lower limb cellulitis changes as the episode runs its course. This will be  
189 influenced by when patients seek clinical review and means that different specialties see clinical  
190 features at varying stages of cellulitis.

191 In general practice, the typical presentation includes older people with co-morbidities such as  
192 heart failure and poor mobility (Participant (P) 11, GP trainee); concerns of possible cellulitis  
193 cases are often raised by district nursing colleagues. Emergency care and acute services often  
194 see people who present with features of systemic compromise (P4, acute medicine consultant).  
195 Both infectious disease and general surgery services often see intravenous drug users who are  
196 at risk of deeper infection (P2, infectious disease consultant; P16, surgical trainee).

197 In dermatology services, presentations were seen later in the episode '*usually the patient is*  
198 *already admitted ..... [the referring team] have tried [multiple antibiotics], but nothing is happening,*  
199 *"please can you come and tell us what is going on?"* (P9, dermatology consultant). This partial  
200 treatment and response can make the diagnosis challenging as the initial typical features of  
201 cellulitis may now vary '*there are varying ranges of erythema, from a little bit of light pinkness to*  
202 *rip roaring hot red, tender, well demarcated, unilateral; the classic sort of textbook stuff* (P18,  
203 dermatology registrar). However, seeing patients later in the journey allowed dermatologists to  
204 appreciate the progression of clinical features '*I learnt to appreciate much more that [cellulitis] is*

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4 205 *coming up, it is happening and that it is fading away....you're looking at this leg that has generally*  
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7 206 *sort of this post inflammatory pinkness, but if you look at patient photos it was much more kind of*  
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10 207 *classical earlier on so it is kind of a reassuring the medical team saying yes this is probably*  
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13 208 *resolving cellulitis at this point ' (P18). Importantly for dermatologists, other more serious*  
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16 209 *pathologies such as a deep vein thrombosis (DVT) had often been ruled out, 'virtually every*  
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19 210 *patient that I see...they have had their d-dimer and their duplex done so [DVT] is usually a*  
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22 211 *diagnosis that has been excluded (P20, dermatology consultant).*

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26 212 Factors that increased the likelihood of cellulitis were: features of systemic upset including fever,  
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29 213 malaise, rigors (P12, GP locum); co-existing injury or infection such as tinea, superficial  
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32 214 ulceration, previous history of cellulitis, previous history of dermatological conditions such as  
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35 215 eczema, diabetes, immunosuppressive medications such as steroids (P19, emergency care  
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38 216 consultant) and those with no fixed abode with social and health risks (P9).

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43 217 *Who should diagnose cellulitis?*

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47 218 When asked about the most ideal HCP to diagnose cellulitis, participants often felt their own  
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50 219 specialty were, but learning from experience was key *'I would say it is just experience [helping*  
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53 220 *diagnosis], a lot of the juniors that come into A&E have not seen that many cellulitis' (P19).*

221 Many nurses felt that they were seeing cellulitis more often than doctors (P11) and this view was  
222 supported by doctors *'[community nurses] probably see [cellulitis] most and are the best placed*  
223 *for it to be diagnosed....cellulitis that walks in and walks out doesn't really need to be in A&E*  
224 (P19).

225 One dermatologist explained how being *'more aware of the differentials'* made them more likely  
226 to accurately diagnose cellulitis, but that ideally cellulitis should be managed in the community as  
227 *'it's a really common condition'* (P15, dermatology consultant).

### 228 *Cases of uncertainty*

229 When discussing cases of uncertainty, where cellulitis was the eventual diagnosis, one  
230 dermatologist described a case of bilateral cellulitis *'you are always told it is never bilateral*  
231 *cellulitis, but it was and they were incredibly unwell'* (P15). Trauma related skin changes was  
232 frequently an initial mis-diagnosis in the emergency department *'one of my nurse practitioners*  
233 *had seen ankle swelling... she thought it was just a sprain but then next day presented [again]*  
234 *and I saw him and it looked more like cellulitis... on close examination I could see a couple of*  
235 *scratches...so that was maybe the source of cellulitis'* (P8, emergency care consultant).

236 When discussing cases of uncertainty, where cellulitis was the initial suspected diagnosis, one

237 GP described a case of venous eczema which was managed with repeated antibiotics *'generally*

238 *anything that is red and hot and on the legs is treated with antibiotics'* (P1, GP). Chronic rashes  
 239 were frequently seen by dermatology '*There are too many chronic rashes that get referred as*  
 240 *cellulitis'* (P18) and infectious disease discussed lymphoma cases initially referred as cellulitis  
 241 '*We did see [patients] coming in with "oh this must be a resistant cellulitis", have got a swollen*  
 242 *limb that might be a little bit red and it turns out to be some horrible form of lymphoma, you maybe*  
 243 *get one or two of them every year'* (P2).

244 A frequent diagnosis of uncertainty for primary and emergency care was DVT, as the clinical  
 245 features of cellulitis can overlap '*one thing that is always a problem in leg swelling...it is difficult*  
 246 *to ascertain between DVT and cellulitis'* (P8). Common differential diagnoses discussed by  
 247 participants, which they observe in their clinical practice, with discriminating features from cellulitis  
 248 are shown in Table 3. Of these, dermatologists mentioned skin specific differentials, GPs included  
 249 non-skin specific differentials, whilst acute physicians and surgeons mentioned more acute  
 250 pathologies.

251 **Table 3:** Differential diagnoses of lower limb cellulitis discussed by participants

Differential diagnoses	Key differentiating factors from cellulitis

Chronic heart failure causing oedema	Chronic, bilateral, lack of mobility, breathless, cardiac history (P1,14)
Venous eczema	Usually chronic with hemosiderin scaling, itching, crusting, likely bilateral, possibly eczema elsewhere on body, less well defined, (P3,15)
Thrombophlebitis	Tender, localised, hard, lumpy rash around an often thickened vein (P3,5,12)
Erythema nodosum	Multiple, discrete swellings (P13)
Deep vein thrombosis	Pain is usually deep in calf rather than superficial, less sharply demarcated and less intense erythema, diffuse swelling of limb, can be young, can be intravenous drug users, high DVT wells score, fewer systemic features (P2,12, 13)
Lymphoedema	Chronic, bilateral, usually less painful, thickened warty skin in the long-term, normal inflammatory markers (P9,18)
Allergic reaction to insect bites	Central puncture mark, itch, when acute, developing lichenified erythema when chronic (P2)
Lipodermatosclerosis	Often bilateral, systemically well, tight non tender skin with inverted champagne bottle appearance (P4, P20)
Necrotising fasciitis	Crepitus, rapidly spreading, septic, very tender (P5, P16)

Wound infection	Local to the wound, covers small area, yellow exudate, strong odour (P10, P16)
Baker's cyst	Unilateral popliteal swelling, suddenly more tender on rupture (P15)

252

## 253 Challenges leading to diagnostic uncertainty

### 254 *A subjective diagnosis*

255 There were multiple challenges with diagnosis identified. A GP explained how there is no specific  
 256 test that can aid diagnosis, thus subjective assessment can lead to different diagnoses '*I think the  
 257 fact that there is no specific diagnostic test and it literally goes on well how does this look  
 258 clinically? And two different people can look at something and come up with two different  
 259 answers, so depending on where they have practiced, how they have practiced and how long  
 260 (P1).*

### 261 *Community challenges*

262 In the community, additional challenges for GPs were not being familiar with the patient's  
 263 background history, when seeing a patient for the first time, or taking over care part way through  
 264 the patient journey (P11). Working as a locum doctor with a lack of follow up often led to treatment

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3 265 when unsure '*you've not met the patient before and sometimes you're not going to be able to*  
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6 266 *follow them up so you probably are more likely to give antibiotics*' (P12). Limited resources to see  
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10 267 patients, such as not being able to conduct an urgent home visit, also influenced diagnosis and  
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13 268 subsequent management '*if you know the patient and you know that they have recurrent cellulitis*  
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16 269 *and someone had seen it like a district nurse and it is Friday afternoon and you can't get out and*  
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19 270 *so you know in that situation yes you would make a judgement call* (P1).

### 21 271 *The role of 'defensive' medicine*

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26 272 HCPs in the community, emergency care and surgery were particularly wary of missing a more  
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29 273 serious diagnosis, which needed to be ruled out first, such as DVT and necrotising fasciitis (NF):  
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31  
32 274 '*I think you would want to rule out DVT first because if you miss that then that is... a problem*' (P1,  
33  
34  
35 275 P16). Many HCPs also mentioned '*sepsis*' when discussing clinical features and diagnosis '*we're*  
36  
37  
38 276 *so much more aware of things like sepsis for example...that I think we are more geared up to*  
39  
40  
41  
42 277 *looking at any kind of signs of infection*' (P10, district nurse). This may be leading to an over  
43  
44  
45 278 diagnosis of cellulitis due to concerns of medico legal complaints '*We're all risk adverse aren't*  
46  
47  
48 279 *we? We would rather make sure we weren't sued because we had missed someone with an*  
49  
50  
51 280 *infection*' (P2).



1  
2  
3 281 One consultant felt that not knowing the mimics made the diagnosis more difficult for junior  
4  
5  
6 282 colleagues '*people don't realise there are mimics out there, they just go red leg equals cellulitis*'  
7  
8  
9  
10 283 (P2). A trainee felt seeing less cellulitis cases during their training compared to their senior  
11  
12  
13 284 colleagues historically and '*not getting as much exposure*' (P18) hindered accurate diagnosis.

### 285 *Patient specific factors*

16  
17  
18  
19 286 People with pigmented skin, lymphoedema (P4) and the group who '*come in none specifically*  
20  
21  
22  
23 287 *unwell ...but there is nothing else to go on, [when] examining the patient* (P5, acute medicine  
24  
25  
26 288 consultant) were particularly difficult to diagnose in the acute setting. Another diagnostic challenge  
27  
28  
29 289 was when a patient presents with chronic skin changes or a recent episode of cellulitis with  
30  
31  
32 290 continuing signs '*people with chronic red [legs], their legs are red most of the time, so it is varying*  
33  
34  
35 291 *degrees of red and the skin takes so long to settle so they could have had cellulitis four weeks*  
36  
37  
38 292 *ago and it is still red*' (P17, advanced nurse practitioner).

### 293 **Strategies to improve diagnosis**

#### 294 *Using time as a guide*

45  
46  
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48  
49 295 In cases where the HCP was not sure of the diagnosis, different strategies were employed. Using  
50  
51  
52 296 time to allow further clinical features to develop, with appropriate safety netting was a commonly  
53  
54  
55 297 used approach '*all you can really do is reassure the patient and say...I don't see any clear*

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2  
3 298 *evidence of cellulitis but we will keep an eye on it.... you give safety net advice to the patients'*  
4  
5  
6  
7 299 (P18). This is easier when follow-up appointments may be available in the community, but was  
8  
9  
10 300 also done in the acute setting '*So if they were well.. then I would bring them back to clinic the next*  
11  
12  
13 301 *day or two'* (P4). But follow-up in secondary care is difficult, often not done (P8) and can be a  
14  
15  
16 302 missed opportunity to learn from incorrect diagnoses previously (P2).

### 303 *Trial of treatment*

304 Some HCPs will start antibiotics for a suspected cellulitis and review the response to help provide  
305 the diagnosis retrospectively '*cellulitis...was the easiest thing to try and treat so I think that*  
306 *definitely pushed [me] to try some antibiotics and see if this is an infection'* (P11). However, the  
307 concerns with this were '*antibiotic resistance and side effects...especially in older groups'* (P3,  
308 GP).

### 309 *Biochemical investigations*

310 In primary care, blood tests and cultures were rarely done to diagnose cellulitis '*if I am thinking*  
311 *about doing blood tests...it is unlikely that I am going to continue managing them in the*  
312 *community'* (P11). Blood cultures were requested by the infectious disease physician if it was an  
313 atypical infection '*toxic bug and their skin is shearing off* (P2), but a challenge is '*in the majority*  
314 *of patients we don't isolate [organisms]* (P20). Swabs were done for discharging wound

1  
2  
3 315 infections, mainly by district nurses '*routinely it is quite the norm*' (P14, dermatology nurse) or  
4  
5  
6 316 prior to discussion with microbiology (P18).  
7  
8  
9

10 317 An emergency physician and surgical trainee explained how blood tests and imaging such as x-  
11  
12  
13 318 rays are important to check for osteomyelitis (P16). The blood tests commonly requested by  
14  
15  
16  
17 319 secondary care HCPs were white cell count (WCC) and C-reactive protein (CRP) for infection  
18  
19  
20 320 with one dermatologist stating how changes in blood test results were important when taking  
21  
22  
23 321 referrals for suspected cellulitis '*[with cellulitis]...you expect a) it is unilateral, b) you want some*  
24  
25  
26 322 *inflammatory markers which are raised, at least a reasonable WCC and CRP and if it is normal it*  
27  
28  
29 323 *is not going to be cellulitis*' (P9). However, one challenge with interpreting blood tests was in the  
30  
31  
32  
33 324 group partially treated with antibiotics, who have improving blood tests but limited clinical  
34  
35  
36 325 response, for which one acute physician added '*I would never not diagnose somebody [with*  
37  
38  
39 326 *cellulitis] just because their inflammatory markers are normal*' (P5).  
40  
41  
42

43 327 A biomarker (P20) or point of care test (P12) for cellulitis were suggested as investigations to aid  
44  
45  
46 328 diagnosis.  
47  
48

49 329 *Seeking advice*  
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3 330 Another approach during uncertainty is to discuss with colleagues. In the community the nurse  
4  
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6  
7 331 may ask the GP to review and vice versa. In hospital, specialists in infectious disease,  
8  
9  
10 332 dermatology, microbiology and general/plastic surgeons are most often contacted for review.  
11  
12  
13 333 The use of technology, specifically photography is a *'good way to see the progression'* of cellulitis  
14  
15  
16 334 and in discussion with colleagues *'we took a photograph of it and...showed it to [the GP] and got*  
17  
18  
19 335 *some antibiotics'* (P10).

### 336 *Further education*

22  
23  
24  
25  
26 337 Many HCPs mentioned teaching sessions to improve diagnosis as *'you very quickly just get*  
27  
28  
29 338 *entrenched in your style of practice, your preferences for diagnoses and it is often good to refresh*  
30  
31  
32 339 (P11), both at the undergraduate and postgraduate level as *'I only did two weeks as a medical*  
33  
34  
35 340 *student and given in general practice something like what is it 20% of consultations have a skin*  
36  
37  
38 341 *element in them?* (P13, GP out of hours). Real life clinical cases was felt to be important for  
39  
40  
41  
42 342 teaching *'Sometimes unless you are seeing it, it is all very well seeing pictures but the pictures*  
43  
44  
45 343 *aren't that helpful sometimes, it is how it feels sometimes that makes a difference and actually*  
46  
47  
48 344 *seeing it in the flesh is very different to seeing even a good quality picture [which] is not the same'*  
49  
50  
51 345 (P13).

1  
2  
3 346 A key area of education amongst HCPs was being aware of differential diagnoses for the first  
4  
5  
6  
7 347 point of access services, *'it is not something people will have put a lot of thought into, the*  
8  
9  
10 348 *differentials, and I think the focus needs to be on teaching the frontline staff* (P15). A trainee who  
11  
12  
13 349 worked in a specialist cellulitis clinic found that seeing many cases helped *'pattern recognition*  
14  
15  
16 350 *and [seeing] variation in progression of the rash'*, thereby appreciating the *'life of rashes'* (P18).

### 351 **The need for an objective diagnostic aid**

#### 352 *A diagnostic algorithm*

353 Many participants mentioned developing a diagnostic algorithm, similar to the Wells score for DVT  
354 *'I think when there is a sort of a criteria it can help to confirm your thinking because a lot of the*  
355 *time it just feels more slightly softer in that it is based on your eye, your individual experience but*  
356 *I think it can be helpful to have those objective measures..if it was accepted and validated as a*  
357 *reasonable measure of cellulitis, I think I would actually use that* (P11). In the community this  
358 would *'not require any more special kit or testing or time'* (P10). This may also help GPs make a  
359 validated clinical decision when colleagues such as district nurses are suspecting cellulitis and  
360 the patient cannot be seen quickly (P12). Nurses often use checklists and this *'just gives you*  
361 *something to think about like oh... I hadn't thought about the heat* (P14). One dermatologist

1  
2  
3 362 suggested that a diagnostic checklist should be more of an educational tool to help rule out other  
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6 363 differential diagnoses 'for a diagnostic checklist you almost want it to be provided as an education  
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9  
10 364 tool with photographs and descriptions.... so that people can put these differential diagnoses into  
11  
12  
13 365 their head (P15).

14  
15  
16 366 One trainee felt that the indices of a checklist would have to reflect how cellulitis changes through  
17  
18  
19 367 the course of the episode 'you would have to develop a criteria that can pick up the...beginning,  
20  
21  
22 368 it is in the middle and it is resolving at the end (P18). Other challenges with developing an  
23  
24  
25 369 algorithm were the number of alternative diagnoses with features that often overlapped with  
26  
27  
28  
29 370 cellulitis and vague initial features 'Because there is such a wide differential...how would you  
30  
31  
32 371 exclude all of those and also it can be quite nonspecific sometimes in the early stages' (P12).  
33  
34  
35 372 Another concern regarding an algorithm was missing outliers 'sometimes the trouble with  
36  
37  
38 373 guidelines, algorithms.... you could probably cover 95% but does it mean that actually the atypical  
39  
40  
41 374 5% then [do not] get diagnosed? (P20).

#### 42 43 44 45 375 *Indices for an algorithm*

46  
47  
48 376 The key clinical features HCPs suggested to include in a diagnostic algorithm for lower limb  
49  
50  
51 377 cellulitis were: unilateral, pain, erythema, warmth of limb, pyrexia, swelling, acute onset, trauma  
52  
53  
54  
55 378 to the limb, break in the skin, single area affected (P13), clear demarcation (P3), exudate, flu like

1  
2  
3 379 malaise, tracking rash (P17), shiny, tensor skin (P8), previous cellulitis, co-existing  
4  
5  
6  
7 380 immunosuppression, co-existing skin conditions, clinical observations for sepsis (P19), negative  
8  
9  
10 381 Wells score (P17) and patient concern. One participant also suggested bullae to be included  
11  
12  
13 382 (P18). No HCP suggested blood tests were a priority in the algorithm, but could be included in a  
14  
15  
16 383 modified algorithm in secondary care, similar to the CURB-65 used for pneumonia severity (P11).  
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## 39 **Discussion**

### 43 **Summary**

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47 390 This study found that the presentation of lower limb cellulitis changes as the episode progresses,  
48  
49  
50 391 leading to variation in the clinical features, seen in different clinical settings. This may be reflected  
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54 392 in the range of typical differential diagnoses that specialities discussed.  
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3 393 Clinical experience was described as an important factor in making a more accurate diagnosis.  
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6 394 However, the clinical reasoning behind a diagnosis were contradictory between some HCPs, such  
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10 395 as the use of blood tests to indicate an infection or whether cellulitis can be 'bilateral'.  
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13 396 A core group of clinical features to diagnose cellulitis were suggested. But the challenge is that  
14  
15  
16  
17 397 these features can overlap with other pathologies, irrespective of how likely these are. More  
18  
19  
20 398 serious pathologies then need to be ruled out first, both for the safety of the patient and to avoid  
21  
22  
23 399 medico-legal consequences.  
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26  
27 400 Suggestions to improve the accuracy of diagnoses included developing a diagnostic algorithm  
28  
29  
30 401 which could objectively help HCPs with different levels of experience. The challenge with a  
31  
32  
33 402 diagnostic algorithm is that it would need to incorporate the various stages of a cellulitis episode  
34  
35  
36 403 and therefore various versions of an algorithm might be required.  
37  
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41 404 Importantly, having a greater understanding of the alternative diagnoses is required, especially  
42  
43  
44 405 when the features are vague, atypical or not responding to antibiotic treatment. Educating both  
45  
46  
47 406 doctors and nurses, using real life clinical scenarios and a focus on differential diagnoses, was  
48  
49  
50 407 also discussed and may be an initial feasible approach to improve diagnostic accuracy.  
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**410 Strengths and limitations**

411 A key strength of this study is the methodology used, with two independent coders following a  
412 standardized codebook. Participants were included nationally around the UK, across various  
413 specialities that commonly diagnose cellulitis, with both nurses and doctors of varying clinical  
414 experience.

415 The major limitation of this study was that some participants were unable to fully describe their  
416 clinical rationale behind diagnostic decisions during the interview. This may be because they have  
417 developed an intuitive, pattern-recognition, approach in decision-making with experience.

418 Furthermore, as the interviewer was a fellow clinician, interviewees may not have fully shared the  
419 details of cases that were misdiagnosed or where diagnoses were delayed due to social  
420 desirability bias or fear of litigation.

**421 Comparison with existing literature**

422 To our knowledge, this is the first interview study undertaken with health care professionals,  
423 discussing their experiences of cellulitis diagnosis. Our findings on the clinical features of cellulitis,

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3 424 differential diagnoses and also the need to be aware of mimics have been described in previous  
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6 425 review articles <sup>7</sup>. A previous scoping review also described cases of misdiagnosis and emerging  
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10 426 approaches to improve diagnoses <sup>5</sup>, which were echoed in this study.  
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12  
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#### 14 427 **Implications for research and practice**

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16  
17 428 This study has highlighted that HCPs need to be aware that cellulitis can present with different  
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20 429 features at various stages of the acute episode and need to consider the cellulitis mimics. With a  
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23  
24 430 current shift in health care resulting in trained nurses now managing more acute presentations,  
25  
26  
27 431 upskilling nurses in cellulitis could be part of the solution.  
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31 432 Many HCPs felt confident in making an accurate diagnosis, often guided by experience and  
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34 433 intuition, but found it difficult to verbalise the key distinguishing features. This makes it difficult for  
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38 434 the clinical experience to be shared amongst other colleagues, especially less experienced or  
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41 435 junior HCPs. To overcome this, further qualitative research is required to identify the clinical  
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43  
44 436 reasoning behind the expert process of making a diagnosis, perhaps using clinical cases and  
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46  
47 437 pictures. This will form the basis of the proposed solution of focused education and clinical  
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49  
50 438 features to be included in a diagnostic aid.  
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3 439 Some indices for a diagnostic algorithm have been identified in this study, as well as key  
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7 440 distinguishing features from differential diagnosis, but these need validating with larger studies  
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10 441 and an expert consensus setting exercise.  
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## 14 442 **Conclusion**

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18 443 This interview study has shown that cellulitis is a complex diagnosis. Not only does the core  
19  
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22 444 features overlap with other diagnoses, the presentation of cellulitis changes as the episode  
23  
24  
25 445 progresses. Although cellulitis is a common diagnosis to make, and whilst further research in  
26  
27  
28 446 developing diagnostic aids needs to be undertaken, simply being aware of the cellulitis mimics  
29  
30  
31 447 may help improve diagnostic accuracy.  
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50 452 of the National Health Service, the National Institute for Health Research or the Department of  
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3 4547 455 **Competing interest**

11 456 None declared

15 457 **Author contributions**19 458 **M Patel** was involved with the design of the study, collection and analysis of data, drafting the  
21 459 manuscript and final approval of the manuscript.23 460 **S I Lee** was involved with the design of the study, analysis of data, drafting the manuscript and  
25 461 final approval of the manuscript.27 462 **NJ Levell** was involved with the design of the study, analysis of data, drafting the manuscript and  
29 463 final approval of the manuscript.31 464 **P Smart** was involved with the design of the study, analysis of data, drafting the manuscript and  
33 465 final approval of the manuscript.35 466 **J Kai** was involved with the design of the study, analysis of data, drafting the manuscript and final  
37 467 approval of the manuscript.39 468 **KS Thomas** was involved with the design of the study, analysis of data, drafting the manuscript  
41 469 and final approval of the manuscript.43 470 **P Leighton** was involved with the design of the study, analysis of data, drafting the manuscript  
45 471 and final approval of the manuscript.

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21 498 **Figure 1: Standardised codebook used by two independent coders**22  
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27 500 **Supplementary Materials**28  
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31 501 **Figure 1: Topic guide used to structure the interview**32  
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## Codes used

- Trial of treatment guides diagnosis
- Discussing diagnosis with colleagues
- Time and safety netting approach
- Patients who self-diagnose and treat
- Approach when HCPs do not agree with patient self-diagnosis
- Patients involved with diagnosis with the HCP
- Typical cellulitis presentations
- Clinical features of cellulitis
- Factors that decrease the likelihood of cellulitis diagnosis
- Factors that increase the likelihood of cellulitis diagnosis
- Investigations to aid diagnosis
- Missed/delayed diagnosis of cellulitis (final diagnosis)
- Missed/delayed diagnosis of cellulitis (initial diagnosis)
- Patient finds it difficult to accept it is not cellulitis
- Reasons why cellulitis diagnosis is challenging
- Suggestions on what may improve diagnosis
- Views on diagnostic aids for HCP
- Views on diagnostic aids for patients
- Views on how well HCP make diagnosis
- Experience guides diagnosis
- Seeing patients part way through assessment and management
- Differential diagnoses
- Sepsis as a concern
- Medico legal issues as a factor
- Follow up of patients
- Most suitable HCP to diagnose cellulitis
- Fear of missing more serious differentials
- Clinical features to include in diagnostic algorithm
- Other factors influencing diagnosis

1 **If the participant has a recent case of cellulitis that they can discuss:**

2 **Can you tell me about a case of cellulitis that you diagnosed?**

3 Prompts:

- 4 • What thoughts go through your head when you are considering a diagnosis of cellulitis?
- 5 • What symptoms do you ask about? Local? General?
- 6 • What signs do you look for? Local? General?
- 7 • Are there any specific signs/symptoms you rely on to help?
- 8 • Did you do any tests?
- 9 • Did you seek advice from anyone else?
- 10 • Were you concerned that this may not be cellulitis?
- 11 • If you were concerned, why?
- 12 • Was there anything challenging about this case?
- 13 • How did you address these challenges?
- 14 • How confident were you that this was cellulitis on a 1-10 scale when you first saw the patient?
- 15 • Did the patient discuss any self-diagnoses?
- 16 • Did any external factors such as time influence your decision?
- 17 • Did the patient come back to see you again?
- 18 • Would you change your approach if the same case presented again?
- 19 • Is this a typical case you see?
- 20 • What are the main differential diagnoses you see?

24 Repeat the above for a maximum two cases that the participants may have for the interview (repeat twice  
25 only if the participant has no delayed/incorrect cases below).

27 **If the participant has a case where the diagnosis was delayed or incorrect (can be initially either  
28 seen by same health care professional or a colleague, but preferably the same person)**

29 Prompts:

- 30 • Did you see the patient on initial presentation or was it a colleague?
- 31 • If it was another colleague, what specialty did they work in?
- 32 • What symptoms did they present with?
- 33 • What signs did they have?
- 34 • What was the initial diagnosis? And why?
- 35 • Were any tests done?
- 36 • Did any external factors influence the decision for the initial diagnosis?
- 37 • When did they see you or another colleague again?
- 38 • If it was another colleague, what specialty did they work in?
- 39 • Did anything change with the signs/symptoms?
- 40 • What happened next?
- 41 • Do you know what the final diagnosis was?
- 42 • What were the reasons for the delay in the diagnosis?
- 43 • Why was it difficult to make an accurate diagnosis on first consultation?

44 **We want to establish if it is possible to determine a core group of features that can be used to help  
45 diagnose lower limb cellulitis**

46 Prompts:

- 47 • What symptoms are you asking about?



- Of these symptoms, which do you think are more suggestive of cellulitis?
- Are there any symptoms that make cellulitis less likely?
- Are there other features in the history which make cellulitis more/less likely? (prompt – other conditions, previous history, drugs, family history )
- What signs are you looking for?
- Of these signs, which do you think are more suggestive of cellulitis?
- Would you request any tests if it was available to you on the same day?
- If so what tests would these be?
- Are there any signs in a 'red leg' that would make cellulitis less likely as the diagnosis?
- Are there any signs in a red leg which would make cellulitis more likely as the diagnosis?
- How has your approach to diagnosing cellulitis changed after managing previous cases?
- If the patient has had previous cellulitis, does this influence your diagnosis?
- From your experience, what differential diagnoses do you think about?
- How do you distinguish cellulitis from these differential diagnoses?
- Specifically, how do you differentiate cellulitis from lymphoedema?
- Specifically, how do you differentiate cellulitis from venous eczema?
- Specifically, how do you differentiate cellulitis from infected venous eczema?
- Specifically, how do you differentiate cellulitis from lymphodermatosclerosis?
- Do you feel that a list of key diagnostic features of cellulitis would help when assessing patients?

**We want your views on some aspects of diagnosis that patients with recurrent cellulitis and lymphoedema have discussed**

- Patients felt that they were confident in making a self-diagnosis of cellulitis and valued greater trust in self-management at home with treatment. What are your thoughts on patients self-diagnosing?
- Would a photograph with a proforma taken and filled in by the patient and sent to you be helpful in managing patients with recurrent cellulitis?
- In the instance where you may not agree with the patients self-diagnosis of cellulitis, how would you manage the diagnosis?
- Do you feel that any further training or resources should be set up to help improve our diagnosis of cellulitis? For example as specialist cellulitis clinic to refer patients to?
- What are your thoughts on health care professionals having a guide such as checklist to help diagnosis?
- Do you think patients should have this checklist? If so why or why not?

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The Editor,  
BMJ Open

2<sup>nd</sup> October 2019

Dear Editor,

We would be grateful if you would consider the enclosed article for publication in your journal.

Helping health care professionals (HCP) to improve diagnosis has been determined as key for future cellulitis research. There is a lack of knowledge about HCPs experiences and challenges in diagnosing suspected lower limb cellulitis.

We sought to explore the experiences and challenges in diagnosing suspected lower limb cellulitis through a national interview study involving doctors and nurses in various specialties including dermatology, primary care and acute services.

Four key themes emerged. The presentation of lower limb cellulitis changes as the episode runs its course. Therefore, different specialties see clinical features at varying stages of cellulitis. Clinical experience is essential to being confident in making a diagnosis, but even amongst experienced HCPs, there were differences in the clinical rationale of diagnosis. A group of core clinical features were suggested, many of which overlapped with alternative diagnoses. This emphasises how the diagnosis is challenging, with objective aids and a greater understanding of the mimics of cellulitis required.

We conclude that cellulitis is a complex diagnosis and has a widely variable clinical presentation at different stages. Although cellulitis is a common diagnosis to make, HCPs need to be mindful of alternative diagnoses.

We hope this article will stimulate further research on the diagnosis of lower limb cellulitis. Cellulitis is of particular interest to many health care professionals in various specialties and therefore we feel this article should target a journal that reaches a wide audience.

All authors declare no conflicts of interest and have read and approved this version. The requirements for authorship have been met.

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If you have any questions concerning this paper please do not hesitate to contact me.

Yours sincerely,

Dr Mitesh Patel MBChB, BSc, PGCert

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<http://www.equator-network.org/reporting-guidelines/srqr/>

Page/line no(s).

### Title and abstract

<p><b>Title</b> - Concise description of the nature and topic of the study Identifying the study as qualitative or indicating the approach (e.g., ethnography, grounded theory) or data collection methods (e.g., interview, focus group) is recommended</p>	Page 1/line 1-2
<p><b>Abstract</b> - Summary of key elements of the study using the abstract format of the intended publication; typically includes background, purpose, methods, results, and conclusions</p>	Page 2/lines 43-67

### Introduction

<p><b>Problem formulation</b> - Description and significance of the problem/phenomenon studied; review of relevant theory and empirical work; problem statement</p>	Page 4/ lines 91-102
<p><b>Purpose or research question</b> - Purpose of the study and specific objectives or questions</p>	Page 4/lines 101-102

### Methods

<p><b>Qualitative approach and research paradigm</b> - Qualitative approach (e.g., ethnography, grounded theory, case study, phenomenology, narrative research) and guiding theory if appropriate; identifying the research paradigm (e.g., postpositivist, constructivist/ interpretivist) is also recommended; rationale**</p>	Page 7/lines 157-158
<p><b>Researcher characteristics and reflexivity</b> - Researchers' characteristics that may influence the research, including personal attributes, qualifications/experience, relationship with participants, assumptions, and/or presuppositions; potential or actual interaction between researchers' characteristics and the research questions, approach, methods, results, and/or transferability</p>	Page 6/ lines 137-140
<p><b>Context</b> - Setting/site and salient contextual factors; rationale**</p>	Page 6/lines 141-144
<p><b>Sampling strategy</b> - How and why research participants, documents, or events were selected; criteria for deciding when no further sampling was necessary (e.g., sampling saturation); rationale**</p>	Pages 5-6/ lines 123-136
<p><b>Ethical issues pertaining to human subjects</b> - Documentation of approval by an appropriate ethics review board and participant consent, or explanation for lack thereof; other confidentiality and data security issues</p>	Page 5/ lines 112-116
<p><b>Data collection methods</b> - Types of data collected; details of data collection procedures including (as appropriate) start and stop dates of data collection and analysis, iterative process, triangulation of sources/methods, and modification of procedures in response to evolving study findings; rationale**</p>	Page 6/ lines 145-151

<b>Data collection instruments and technologies</b> - Description of instruments (e.g., interview guides, questionnaires) and devices (e.g., audio recorders) used for data collection; if/how the instrument(s) changed over the course of the study	Page 6/ lines 145-151
<b>Units of study</b> - Number and relevant characteristics of participants, documents, or events included in the study; level of participation (could be reported in results)	In the results, Page 8/lines 175-176 and Table 1
<b>Data processing</b> - Methods for processing data prior to and during analysis, including transcription, data entry, data management and security, verification of data integrity, data coding, and anonymization/de-identification of excerpts	Page 6/ lines 152-154
<b>Data analysis</b> - Process by which inferences, themes, etc., were identified and developed, including the researchers involved in data analysis; usually references a specific paradigm or approach; rationale**	Page 7/lines 156-162
<b>Techniques to enhance trustworthiness</b> - Techniques to enhance trustworthiness and credibility of data analysis (e.g., member checking, audit trail, triangulation); rationale**	Page 7/ lines 159-162

### Results/findings

<b>Synthesis and interpretation</b> - Main findings (e.g., interpretations, inferences, and themes); might include development of a theory or model, or integration with prior research or theory	Pages 8-19/ lines 174-383
<b>Links to empirical data</b> - Evidence (e.g., quotes, field notes, text excerpts, photographs) to substantiate analytic findings	Pages 8-19/ lines 174-383

### Discussion

<b>Integration with prior work, implications, transferability, and contribution(s) to the field</b> - Short summary of main findings; explanation of how findings and conclusions connect to, support, elaborate on, or challenge conclusions of earlier scholarship; discussion of scope of application/generalizability; identification of unique contribution(s) to scholarship in a discipline or field	Page 20/lines 389-407, Page 21-22/ Lines 421-441
<b>Limitations</b> - Trustworthiness and limitations of findings	Page 21/ lines 410-420

### Other

<b>Conflicts of interest</b> - Potential sources of influence or perceived influence on study conduct and conclusions; how these were managed	Page 23/line 453-454
<b>Funding</b> – Sources of funding and other support; role of funders in data collection, interpretation, and reporting	Page 1/ lines 22-23

\*The authors created the SRQR by searching the literature to identify guidelines, reporting standards, and critical appraisal criteria for qualitative research; reviewing the reference lists of retrieved sources; and contacting experts to gain feedback. The SRQR aims to improve the transparency of all aspects of qualitative research by providing clear standards for reporting qualitative research.

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\*\*The rationale should briefly discuss the justification for choosing that theory, approach, method, or technique rather than other options available, the assumptions and limitations implicit in those choices, and how those choices influence study conclusions and transferability. As appropriate, the rationale for several items might be discussed together.

**Reference:**

O'Brien BC, Harris IB, Beckman TJ, Reed DA, Cook DA. **Standards for reporting qualitative research: a synthesis of recommendations.** *Academic Medicine*, Vol. 89, No. 9 / Sept 2014  
DOI: 10.1097/ACM.0000000000000388

For peer review only



University of  
Nottingham  
UK | CHINA | MALAYSIA

***A qualitative study to determine the health care professionals' experience of the diagnosis of lower limb cellulitis***

**Final Version 1.0  
31.10.2018**

**Short title:** Diagnosing lower limb cellulitis

**IRAS Project ID:** 254088

**Study Sponsor:** University of Nottingham

**Sponsor reference:** 18072

**Funding Source:** Funding from the RCGP Practitioners allowance will be sought, providing a maximum of £2000. The application form requires the sponsor to agree to act as a research sponsor and so will be submitted after this ethics application has been submitted.

## STUDY PERSONNEL AND CONTACT DETAILS

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Diagnosing lower limb cellulitis  
 - Final Version 1.0 Date 31.10.2018

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Dr Peter Smart  
Patient representative

Title	A qualitative study to determine health care professionals' experience of the diagnosis of lower limb cellulitis
Short title	Diagnosing lower limb cellulitis
Chief Investigator	Professor Kim S Thomas
Objectives	<ul style="list-style-type: none"> <li>Describe the key clinical features which inform the diagnosis of lower limb cellulitis</li> <li>Explore the difficulties in making a diagnosis of lower limb cellulitis</li> </ul>
Study Configuration	Semi-structured interviews with health care professionals regarding lower limb cellulitis
Setting	Primary and secondary care
Number of participants	Approximately 20
Eligibility criteria	Age >18 years All ethnicities Be a qualified health care professional

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**Study Coordinating Centre:** Centre of Evidence Based Dermatology  
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Page 3 of 20

Diagnosing lower limb cellulitis  
- Final Version 1.0 Date 31.10.2018

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	<p>Have managed a clinical case of suspected cellulitis of the lower limb in the UK</p> <p>A minimum of two years clinical experience as a health care professional, which includes managing lower limb cellulitis</p> <p>Able to give informed consent</p> <p>Speak English language</p>
Description of interventions	One face-to-face or telephone interview lasting 45-60 minutes
Duration of study	February 2019- July 2019
Methods of analysis	Framework thematic analysis

## SYNOPSIS

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## ABBREVIATIONS

CI	Chief Investigator overall
CRF	Case Report Form
GCP	Good Clinical Practice
NHS	National Health Service
PI	Principal Investigator at a local centre
PIS	Participant Information Sheet
REC	Research Ethics Committee
R&D	Research and Development department
UoN	University of Nottingham
CEBD	Centre of Evidence Based Dermatology
RCGP	Royal College of General Practitioners

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## STUDY BACKGROUND INFORMATION AND RATIONALE

Cellulitis is an acute bacterial inflammation of the dermis and associated subcutaneous tissue, with 60% of cases affecting the lower limb<sup>1</sup>. The diagnosis of cellulitis can be challenging, with 31% of presentations of suspected lower limb cellulitis in the emergency department found to be other diagnoses<sup>2</sup>. Routine biochemical and haematology blood tests and blood cultures are not specific for cellulitis<sup>3</sup>. This results in avoidable hospital admissions and unnecessary antibiotic prescribing<sup>4</sup>. Definitive diagnostic criteria would also improve the validity of clinical research on cellulitis<sup>5</sup>, but there are no agreed diagnostic criteria for cellulitis.

Cellulitis cases commonly present to primary care services or the emergency department<sup>6</sup>. A recent cellulitis research priority setting partnership (PSP), ranked questions on 'diagnostic criteria' and identifying early signs and symptoms as important for future cellulitis research<sup>7</sup>.

A scoping review we conducted, showed 44 different pathologies misdiagnosed as cellulitis on initial presentation (accepted with changes, British Journal of Dermatology).

A systematic review we carried out, showed that there are no robustly developed and validated diagnostic tools or criteria for lower limb cellulitis (in submission, British Journal of Dermatology). Despite eight potential tools having been explored so far: biochemical tests, imaging, predictive scoring and clinical features, they all provide limited clinical applicability and validity.

No previous qualitative studies have addressed the challenges in diagnosing suspected cellulitis from the health care professionals (HCP) perspective.

## STUDY OBJECTIVES AND PURPOSE

### PURPOSE

This study will help to establish the core features described by health care professionals (HCP) when they suspect a patient may have lower limb cellulitis. This will also help answer the question 'what are the early signs and symptoms of cellulitis that can help ensure speedy treatment': a priority from the cellulitis PSP. Furthermore, this study will also support further research on the development of diagnostic criteria for lower limb cellulitis.

### OBJECTIVES

#### Primary

- Describe the key clinical features which inform the diagnosis of lower limb cellulitis

#### Secondary

- Explore the difficulties in making a diagnosis of lower limb cellulitis

## STUDY DESIGN

### STUDY CONFIGURATION

Face-to-face or telephone interviews, lasting approximately 45-60 minutes will be conducted with health care professionals (HCPs). A purposive sample will be selected, with HCPs

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Diagnosing lower limb cellulitis  
- Final Version 1.0 Date 31.10.2018

(doctors and nurses) from: general practice, dermatology, tissue viability service, lymphoedema service and either the emergency department or acute medicine.

## STUDY MANAGEMENT

The study will be managed from the central coordinating centre (CEBD, University of Nottingham).

The Chief Investigator (CI) has overall responsibility for the study and shall oversee all study management.

The data custodian will be the CI.

## DURATION OF THE STUDY AND PARTICIPANT INVOLVEMENT

Study Duration: Interviews will start in February 2019 and is expected to be completed by July 2019. The total duration will be six months.

Participant Duration: Each participant will take part in an interview that will last 45-60 minutes. No follow up interviews are planned. Participants will receive a summary of the study findings unless they specifically ask not to receive them. It is anticipated that up to 20 participants will be required, however more HCPs will be included if new themes emerge.

### End of the Study

The end of the study will be the last interview.

## SELECTION AND WITHDRAWAL OF PARTICIPANTS

### Recruitment

Doctors and nurses from: general practice, dermatology, tissue viability service, lymphoedema service and either the emergency department or acute medicine, will be recruited.

Recruitment will be opportunistic in the first instance, using a sampling frame to ensure a broad representation of participants. HCPs will be emailed, briefly discussing the aims of the study, inclusion criteria and methods of the study. HCPs will be approached through:

- A pre-existing cellulitis database, co-ordinated at the Centre of Evidence Based Dermatology (CEBD), which includes general practitioners (GPs), dermatologists, emergency physicians, lymphoedema specialists and nurses. They have previously been involved with cellulitis research at the CEBD and have consented to being approached for future cellulitis studies.
- The UK Dermatology clinical trials network, co-ordinated at the CEBD, includes a broad membership of GPs, dermatologists and nurses who have consented to being approached about future dermatology studies.
- The British Association of Dermatologists, Society of Acute Medicine, Royal College of Emergency Medicine, Nottinghamshire Local Medical Committee for GPs and Primary Care Dermatology Society have agreed to advertise in their newsletters.
- Emergency department and acute medicine physicians/nurses will be recruited from Nottingham University Hospitals NHS Trust, through contacting the clinical leads of each speciality.
- GPs will be recruited by contacting seven clinical commissioning groups (CCG) leads in Nottingham.

- Dermatologists and dermatology nurses will be approached from the cellulitis clinic at Norwich and Norfolk University Hospital, with the help of NL (co-applicant) who helped set up the clinic.
- Snowball sampling where participants help recruit other participants.
- Snowball sampling where current clinical colleagues can help to recruit.
- Additional regulatory bodies such as the Royal College of Nursing and British Lymphology society.

If participation uptake is low, HCPs who have worked with members of the research team will be pragmatically approached. These HCPs will have typical demographics for which we are including in this study.

The local researcher will inform the participant of all aspects pertaining to participation in the study. All HCPs in the UK communicate in English and therefore the consent forms and information sheets will not be available printed in other languages.

It will be explained to the potential participant that entry into the study is entirely voluntary and that they can withdraw at any time but attempts will be made to avoid this occurrence. In the event of their withdrawal it will be explained that their data collected so far cannot be erased and we will use the data in the final analyses where appropriate.

### **Eligibility criteria**

#### **Inclusion criteria**

Age >18 years

All ethnicities

Be a qualified health care professional

Have managed a clinical case of suspected cellulitis of the lower limb in the UK

A minimum of two years clinical experience as a health care professional, which includes managing lower limb cellulitis

Able to give informed consent

Speak English language

#### **Exclusion criteria**

None

#### **Expected duration of participant participation**

Study participants will be participating in the study for 45-60 minutes.

#### **Participant Withdrawal**

Participants may be withdrawn from the study at their own request. Participants will be made aware (via the information sheet and consent form) that should they withdraw the data collected to date cannot be erased and may still be used in the final analysis.

#### **Informed consent**

The Investigator will contact the participant by email before the interview to explain the details of the study and provide a Participant Information Sheet and Consent Form, ensuring that the

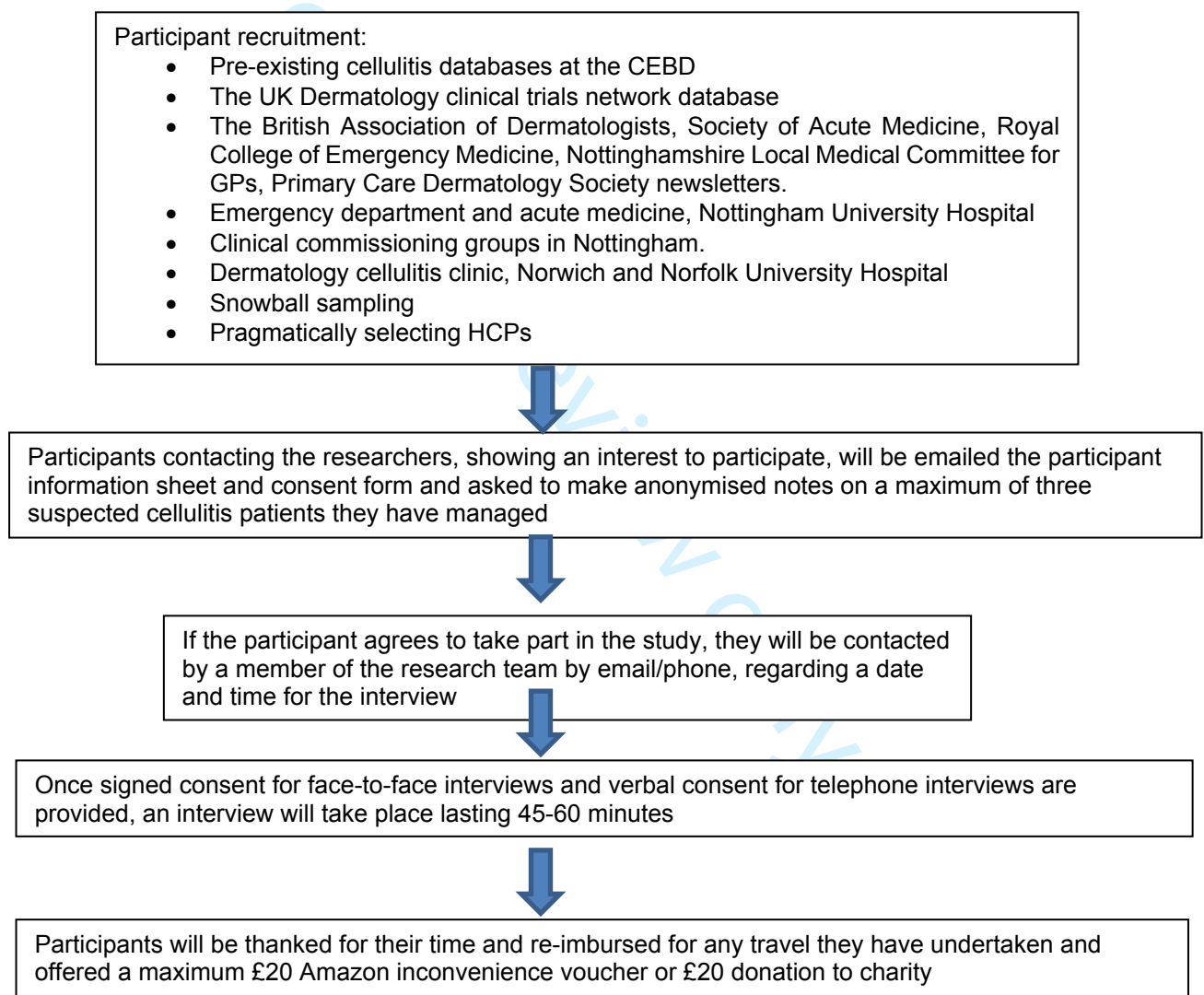
participant has sufficient time to consider participating or not. The Investigator will answer any questions that the participant has concerning study participation.

For participants giving a face-to-face interview, the Consent Form will be signed and dated by the participant before the interview. One copy of the Consent Form will be kept by the participant and one will be kept by the Investigator. On commencing the recording, the participants will be asked to confirm that they have given consent to take part and for the interview to be digitally recorded. For telephone interviews, formal, recorded verbal consent will be gained before the interview and this consent will be transcribed, as a way of documenting this.

## STUDY REGIMEN

The individual steps that each participant will undertake are shown in Figure 1:

Figure 1: Study procedure



Interviews will take place at a place of convenience for the participant or by telephone. If the participant is interviewed at home, the University of Nottingham Lone Working Procedure will be adhered to. The interviews will be conducted by a member of the research team and



1  
2 recorded. Transcription of data will be undertaken by a member of the research team, or a  
3 transcription service affiliated with the University of Nottingham. A set series of questions will  
4 be used for the first two interviews, but may be adapted based on the findings of these  
5 interviews.  
6

## 7 **Compliance**

8 We do not expect any compliance issues.  
9

## 10 **Criteria for terminating the study**

11 None.  
12

## 13 **ANALYSES**

### 14 **Methods**

15  
16 A semi-structured interview guide (see attached document) has been developed around topic  
17 themes from existing literature and in our scoping review (see Box 1), however, this is flexible  
18 to allow unanticipated themes to emerge. Participants recruited will be asked in the initial email  
19 with the participant information sheet and consent form, to make anonymised notes on a  
20 maximum of three cases of cellulitis they have managed, to discuss in the interview. They will  
21 be asked to make notes on the following topics: signs, symptoms, tests used, challenges  
22 encountered with making a diagnosis, learning points for future cases.  
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#### 30 **Box 1: Interview topic themes**

31 Themes 1: Clinical features of suspected cellulitis

32 Themes 2: Experiences of diagnosis  
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36

37 All interviews will be audio-recorded and transcribed verbatim, with participant numbers  
38 assigned to avoid any personal identifiers.  
39

40 All idiosyncratic features that add no meaning to the transcript will be removed. The cleaned  
41 transcripts will then be formatted for read-in compatibility with the data management software,  
42 password protected and stored on the secure server at the University of Nottingham.  
43

44 The data transcripts will be organised using the qualitative software package QSR NVivo 12.  
45 The data will then be handled following the conventions of framework analysis<sup>8</sup>. A broad  
46 analytic framework based upon the topic themes and interview questions will be constructed,  
47 and subsequently refined by coding a small number of transcripts<sup>9</sup>. Coding will be done by  
48 one researcher (MP) and validated by an independent reviewer (JK, KT or PL). All other data  
49 will be charted to the refined framework. Once charting has been completed, thematic matrices  
50 can be interpreted and summaries of each theme / sub-theme produced (Appendix 1).  
51 Comparisons will be made between the data from different specialities.  
52  
53  
54

## 55 **Data storage**

Copies of the audio data files will be uploaded to a secure electronic platform to allow data transfer between the study team and the transcriber. Once the transcripts have been generated, uploaded to the platform, and retrieved by the study team, the audio files will be deleted from the platform. All raw audio data files and transcripts will be encrypted, password protected and stored on a secure server at the University of Nottingham.

### **Sample size and justification**

We approximate that 20 participants will be included as a purposive sample. This number has been chosen because it is feasible to include within the limits of study funding and time. We aim to recruit both doctors and nurses in specialties of general practice, dermatology and either the emergency department or acute medicine, as all these three specialties manage cellulitis frequently. All participants need to have at least two years of clinical experience, as this will include HCPs who have specialist registration and will likely have more clinical experience of cellulitis.

We aim to include an equal number of men and women, with varying number of years of clinical experience as their clinical experiences will change with time. With regards to the GPs and emergency care staff, we want to include both those with more specialist dermatology or infection expertise, and those without.

### **ADVERSE EVENTS**

The occurrence of an adverse event as a result of participation within this study is not expected and no adverse event data will be collected.

### **ETHICAL AND REGULATORY ASPECTS**

If confidential information, defined as information that may identify an individual or place, is shared during the interview, then this will be omitted from the saved copy of the transcript.

The researchers will not impart any medical judgements or opinions. However, if information is shared that may have affected patient safety, then this will be discussed with the CI and escalated as required.

### **ETHICS COMMITTEE AND REGULATORY APPROVALS**

The study will not be initiated before the protocol, consent forms and participant information sheets have received approval / favourable opinion from the Research Ethics Committee (REC), the respective National Health Service (NHS) or other healthcare provider's Research & Development (R&D) department. Should a protocol amendment be made that requires REC approval, the changes in the protocol will not be instituted until the amendment and revised informed consent forms and participant information sheets (if appropriate) have been reviewed and received approval / favourable opinion from the REC and R&D departments. A protocol amendment intended to eliminate an apparent immediate hazard to participants may be implemented immediately providing that the REC are notified as soon as possible and an approval is requested. Minor protocol amendments only for logistical or administrative changes may be implemented immediately; and the REC will be informed.

1  
2 The study will be conducted in accordance with the ethical principles that have their origin in  
3 the Declaration of Helsinki, 1996; the principles of Good Clinical Practice, and the UK Policy  
4 Framework for Health and Social Care Research 2017.  
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6  
7

## 8 **INFORMED CONSENT AND PARTICIPANT INFORMATION**

9 The process for obtaining participant informed consent will be in accordance with the REC  
10 guidance, and Good Clinical Practice (GCP) and any other regulatory requirements that might  
11 be introduced. The investigator and the participant shall both sign and date the Consent Form,  
12 for face-to face interviews, before the person can participate in the study. Recorded verbal  
13 consent will be taken for telephone interviews before participation and the Consent Form  
14 posted after the interview to sign and return to the research team.  
15

16 The participant will receive a copy of the signed and dated forms and the original will be  
17 retained in the Study records.  
18

## 19 **RECORDS**

### 20 **Case report form**

21 Each participant will be assigned a participant number. There will be one case report form  
22 (CRF), keeping a record of all: participant's name, date of birth and participant study number.  
23 This form will be stored in a secure file that only the researchers can access. In line with the  
24 UoN data storage procedures, data will be stored for at least 7 years.  
25  
26

27 This CRF will be treated as confidential documents and held securely in accordance with  
28 regulations. The CRF shall be restricted to those personnel approved by the CI and recorded  
29 as such in the study records.  
30  
31

32 All paper forms shall be filled in using black ballpoint pen. Errors shall be lined out but not  
33 obliterated by using correction fluid and the correction inserted, initialled and dated.  
34  
35

### 36 **Source documents**

37 Source documents shall be filed at the investigator's site and may include but are not limited  
38 to, consent forms, study records, interview transcriptions and audio records. Only study staff  
39 shall have access to study documentation other than the regulatory requirements listed below.  
40  
41

### 42 **Direct access to source data / documents**

43 All source documents shall be made available at all times for review by the CI, Sponsor's  
44 designee and inspection by relevant regulatory authorities.  
45  
46  
47  
48  
49

## 50 **DATA PROTECTION**

51 All study staff and investigators will endeavour to protect the rights of the study's participants  
52 to privacy and informed consent, and will adhere to the current UK General Data Protection  
53 regulation (GDPR). The CRF will only collect the minimum required information for the  
54 purposes of the study. The CRF will be held securely, in a locked room, or locked cupboard or  
55 cabinet. Access to the information will be limited to the study staff and investigators and any  
56 relevant regulatory authorities. Computer held data including the study database will be held  
57

1  
2 securely and password protected. All data will be stored on a secure dedicated web server.  
3 Access will be restricted by user identifiers and passwords (encrypted using a one way  
4 encryption method).  
5

6 Electronic data will be backed up every 24 hours to both local and remote media in encrypted  
7 format.  
8

9 Any medical information provided will be kept confidential.  
10

## 11 **QUALITY ASSURANCE & AUDIT**

  
12

### 13 **INSURANCE AND INDEMNITY**

14 Insurance and indemnity for clinical study participants and study staff is covered within the  
15 NHS Indemnity Arrangements for clinical negligence claims in the NHS, issued under cover of  
16 HSG (96)48. There are no special compensation arrangements, but study participants may  
17 have recourse through the NHS complaints procedures.  
18  
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20 The University of Nottingham as research Sponsor indemnifies its staff, research  
21 participants and research protocols with both public liability insurance and clinical trials  
22 insurance. These policies include provision for indemnity in the event of a successful litigious  
23 claim for proven non-negligent harm.  
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### 26 **STUDY CONDUCT**

27 Study conduct may be subject to systems audit for inclusion of essential documents;  
28 permissions to conduct the study; CVs of study staff and training received; local document  
29 control procedures; consent procedures and recruitment logs; adherence to procedures  
30 defined in the protocol (e.g. inclusion / exclusion criteria, timeliness of visits); accountability of  
31 study materials and equipment calibration logs.  
32  
33

### 34 **STUDY DATA**

35 Monitoring of study data shall include confirmation of informed consent; data storage and data  
36 transfer procedures; local quality control checks and procedures, back-up and disaster  
37 recovery of any local databases.  
38  
39

40 Study data and evidence of monitoring and systems audits will be made available for inspection  
41 by the ethics committee as required.  
42  
43

### 44 **RECORD RETENTION AND ARCHIVING**

45 In compliance with the University of Nottingham Code of Research Conduct and Research  
46 Ethics, the CI will maintain all records and documents regarding the conduct of the study.  
47 These will be retained for at least 7 years or for longer if required. If the responsible investigator  
48 is no longer able to maintain the study records, a second person will be nominated to take over  
49 this responsibility.  
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52 The study documents held by the CI on behalf of the Sponsor shall be finally archived at secure  
53 archive facilities at the University of Nottingham. This archive shall include all anonymised  
54 transcripts, study databases and associated meta-data encryption codes.  
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## DISCONTINUATION OF THE STUDY BY THE SPONSOR

The Sponsor reserves the right to discontinue this study at any time for failure to meet expected enrolment goals, for safety or any other administrative reasons. The Sponsor shall take advice as appropriate in making this decision.

## STATEMENT OF CONFIDENTIALITY

Individual participant medical or personal information obtained as a result of this study are considered confidential and disclosure to third parties is prohibited with the exceptions noted above.

If information is disclosed during the study that could pose a risk of harm to the participant or others, the researcher will discuss this with the CI and where appropriate report accordingly.

Data generated as a result of this study will be available for inspection on request by the participating physicians, the University of Nottingham representatives, the REC, local R&D Departments and the regulatory authorities.

## PUBLICATION AND DISSEMINATION POLICY

The study results will be published in a peer reviewed academic journal and presented at conferences. All the participants will be sent the results, unless they request not to receive them. The manuscript will follow the Standards for Reporting Qualitative Research (SRQR) recommendations.

Participants will not be identifiable in the dissemination of results.

## USER AND PUBLIC INVOLVEMENT

This study was developed from priorities in cellulitis research identified by patients at the cellulitis PSP. A patient with cellulitis, as a collaborator, has helped in the design of this protocol.

The results will also be discussed at the annual CEBD patient panel, with patients with various skin diseases present, including cellulitis.

## STUDY FINANCES

### Funding source

Funding from the RCGP Practitioners allowance will be sought, providing a maximum of £2000. The application form requires the sponsor to agree to act as a research sponsor and so will be submitted after this ethics application has been submitted.

### Participant stipends and payments

Participants will be offered a £20 amazon inconvenience voucher, or a £20 donation to charity on their behalf, to participate in the study. This will ensure a gesture of gratitude, without influencing the participant response.

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Diagnosing lower limb cellulitis  
- Final Version 1.0 Date 31.10.2018

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3 Travel expenses will be provided for participants to attend a face-to-face interview.  
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For peer review only

**SIGNATURE PAGES**

Signatories to Protocol:

**Chief Investigator:** (name) \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

For peer review only

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## Appendix 1



Themes and sub-themes we believe may be described in the study

Key themes	Sub-themes
Diagnosis	Symptoms asked Signs sought Tests done Decision making aids
Challenges	Differential diagnoses Time as a factor Patient expectation Previous experiences Knowledge gap Confidence in making a diagnosis

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University of  
**Nottingham**  
UK | CHINA | MALAYSIA

***A qualitative study to determine the health care professionals' experience of the diagnosis of lower limb cellulitis***

**Final Version 1.0  
31.10.2018**

**Short title:** Diagnosing lower limb cellulitis

**IRAS Project ID:** 254088

**Study Sponsor:** University of Nottingham

**Sponsor reference:** 18072

**Funding Source:** Funding from the RCGP Practitioners allowance will be sought, providing a maximum of £2000. The application form requires the sponsor to agree to act as a research sponsor and so will be submitted after this ethics application has been submitted.

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Diagnosing lower limb cellulitis  
- Final Version 1.0 Date 31.10.2018

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## SYNOPSIS

Title	A qualitative study to determine health care professionals' experience of the diagnosis of lower limb cellulitis
Short title	Diagnosing lower limb cellulitis
Chief Investigator	Professor Kim S Thomas
Objectives	<ul style="list-style-type: none"> <li>Describe the key clinical features which inform the diagnosis of lower limb cellulitis</li> <li>Explore the difficulties in making a diagnosis of lower limb cellulitis</li> </ul>
Study Configuration	Semi-structured interviews with health care professionals regarding lower limb cellulitis
Setting	Primary and secondary care
Number of participants	Approximately 20
Eligibility criteria	<p>Age &gt;18 years  All ethnicities  Be a qualified health care professional  Have managed a clinical case of suspected cellulitis of the lower limb in the UK  A minimum of two years clinical experience as a health care professional, which includes managing lower limb cellulitis  Able to give informed consent  Speak English language</p>
Description of interventions	One face-to-face or telephone interview lasting 45-60 minutes
Duration of study	February 2019- July 2019
Methods of analysis	Framework thematic analysis

## ABBREVIATIONS

CI	Chief Investigator overall
CRF	Case Report Form
GCP	Good Clinical Practice
NHS	National Health Service
PI	Principal Investigator at a local centre
PIS	Participant Information Sheet
REC	Research Ethics Committee
R&D	Research and Development department
UoN	University of Nottingham
CEBD	Centre of Evidence Based Dermatology
RCGP	Royal College of General Practitioners

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## STUDY BACKGROUND INFORMATION AND RATIONALE

Cellulitis is an acute bacterial inflammation of the dermis and associated subcutaneous tissue, with 60% of cases affecting the lower limb <sup>1</sup>. The diagnosis of cellulitis can be challenging, with 31% of presentations of suspected lower limb cellulitis in the emergency department found to be other diagnoses <sup>2</sup>. Routine biochemical and haematology blood tests and blood cultures are not specific for cellulitis <sup>3</sup>. This results in avoidable hospital admissions and unnecessary antibiotic prescribing <sup>4</sup>. Definitive diagnostic criteria would also improve the validity of clinical research on cellulitis <sup>5</sup>, but there are no agreed diagnostic criteria for cellulitis.

Cellulitis cases commonly present to primary care services or the emergency department <sup>6</sup>. A recent cellulitis research priority setting partnership (PSP), ranked questions on 'diagnostic criteria' and identifying early signs and symptoms as important for future cellulitis research <sup>7</sup>.

A scoping review we conducted, showed 44 different pathologies misdiagnosed as cellulitis on initial presentation (accepted with changes, British Journal of Dermatology).

A systematic review we carried out, showed that there are no robustly developed and validated diagnostic tools or criteria for lower limb cellulitis (in submission, British Journal of Dermatology). Despite eight potential tools having been explored so far: biochemical tests, imaging, predictive scoring and clinical features, they all provide limited clinical applicability and validity.

No previous qualitative studies have addressed the challenges in diagnosing suspected cellulitis from the health care professionals (HCP) perspective.

## STUDY OBJECTIVES AND PURPOSE

### PURPOSE

This study will help to establish the core features described by health care professionals (HCP) when they suspect a patient may have lower limb cellulitis. This will also help answer the question 'what are the early signs and symptoms of cellulitis that can help ensure speedy treatment': a priority from the cellulitis PSP. Furthermore, this study will also support further research on the development of diagnostic criteria for lower limb cellulitis.

### OBJECTIVES

#### Primary

- Describe the key clinical features which inform the diagnosis of lower limb cellulitis

#### Secondary

- Explore the difficulties in making a diagnosis of lower limb cellulitis

## STUDY DESIGN

## STUDY CONFIGURATION

Face-to-face or telephone interviews, lasting approximately 45-60 minutes will be conducted with health care professionals (HCPs). A purposive sample will be selected, with HCPs

(doctors and nurses) from: general practice, dermatology, tissue viability service, lymphoedema service and either the emergency department or acute medicine.

## STUDY MANAGEMENT

The study will be managed from the central coordinating centre (CEBD, University of Nottingham).

The Chief Investigator (CI) has overall responsibility for the study and shall oversee all study management.

The data custodian will be the CI.

## DURATION OF THE STUDY AND PARTICIPANT INVOLVEMENT

Study Duration: Interviews will start in February 2019 and is expected to be completed by July 2019. The total duration will be six months.

Participant Duration: Each participant will take part in an interview that will last 45-60 minutes. No follow up interviews are planned. Participants will receive a summary of the study findings unless they specifically ask not to receive them. It is anticipated that up to 20 participants will be required, however more HCPs will be included if new themes emerge.

### End of the Study

The end of the study will be the last interview.

## SELECTION AND WITHDRAWAL OF PARTICIPANTS

### Recruitment

Doctors and nurses from: general practice, dermatology, tissue viability service, lymphoedema service and either the emergency department or acute medicine, will be recruited.

Recruitment will be opportunistic in the first instance, using a sampling frame to ensure a broad representation of participants. HCPs will be emailed, briefly discussing the aims of the study, inclusion criteria and methods of the study. HCPs will be approached through:

- A pre-existing cellulitis database, co-ordinated at the Centre of Evidence Based Dermatology (CEBD), which includes general practitioners (GPs), dermatologists, emergency physicians, lymphoedema specialists and nurses. They have previously been involved with cellulitis research at the CEBD and have consented to being approached for future cellulitis studies.
- The UK Dermatology clinical trials network, co-ordinated at the CEBD, includes a broad membership of GPs, dermatologists and nurses who have consented to being approached about future dermatology studies.
- The British Association of Dermatologists, Society of Acute Medicine, Royal College of Emergency Medicine, Nottinghamshire Local Medical Committee for GPs and Primary Care Dermatology Society have agreed to advertise in their newsletters.
- Emergency department and acute medicine physicians/nurses will be recruited from Nottingham University Hospitals NHS Trust, through contacting the clinical leads of each speciality.
- GPs will be recruited by contacting seven clinical commissioning groups (CCG) leads in Nottingham.

- Dermatologists and dermatology nurses will be approached from the cellulitis clinic at Norwich and Norfolk University Hospital, with the help of NL (co-applicant) who helped set up the clinic.
- Snowball sampling where participants help recruit other participants.
- Snowball sampling where current clinical colleagues can help to recruit.
- Additional regulatory bodies such as the Royal College of Nursing and British Lymphology society.

If participation uptake is low, HCPs who have worked with members of the research team will be pragmatically approached. These HCPs will have typical demographics for which we are including in this study.

The local researcher will inform the participant of all aspects pertaining to participation in the study. All HCPs in the UK communicate in English and therefore the consent forms and information sheets will not be available printed in other languages.

It will be explained to the potential participant that entry into the study is entirely voluntary and that they can withdraw at any time but attempts will be made to avoid this occurrence. In the event of their withdrawal it will be explained that their data collected so far cannot be erased and we will use the data in the final analyses where appropriate.

### **Eligibility criteria**

#### **Inclusion criteria**

Age >18 years

All ethnicities

Be a qualified health care professional

Have managed a clinical case of suspected cellulitis of the lower limb in the UK

A minimum of two years clinical experience as a health care professional, which includes managing lower limb cellulitis

Able to give informed consent

Speak English language

#### **Exclusion criteria**

None

#### **Expected duration of participant participation**

Study participants will be participating in the study for 45-60 minutes.

#### **Participant Withdrawal**

Participants may be withdrawn from the study at their own request. Participants will be made aware (via the information sheet and consent form) that should they withdraw the data collected to date cannot be erased and may still be used in the final analysis.

#### **Informed consent**

The Investigator will contact the participant by email before the interview to explain the details of the study and provide a Participant Information Sheet and Consent Form, ensuring that the

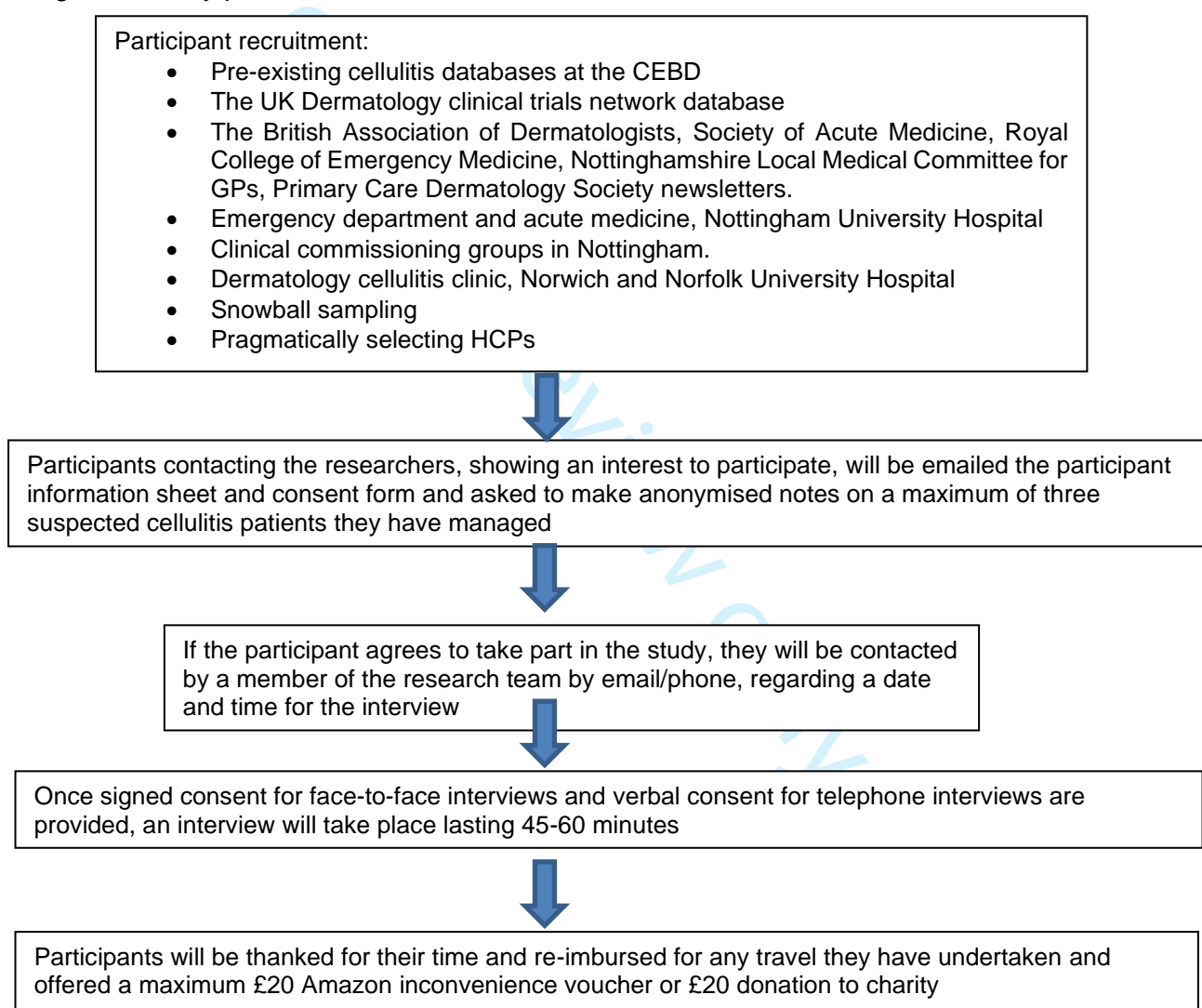
participant has sufficient time to consider participating or not. The Investigator will answer any questions that the participant has concerning study participation.

For participants giving a face-to-face interview, the Consent Form will be signed and dated by the participant before the interview. One copy of the Consent Form will be kept by the participant and one will be kept by the Investigator. On commencing the recording, the participants will be asked to confirm that they have given consent to take part and for the interview to be digitally recorded. For telephone interviews, formal, recorded verbal consent will be gained before the interview and this consent will be transcribed, as a way of documenting this.

## STUDY REGIMEN

The individual steps that each participant will undertake are shown in Figure 1:

Figure 1: Study procedure



Interviews will take place at a place of convenience for the participant or by telephone. If the participant is interviewed at home, the University of Nottingham Lone Working Procedure will be adhered to. The interviews will be conducted by a member of the research team and

1  
2 recorded. Transcription of data will be undertaken by a member of the research team, or a  
3 transcription service affiliated with the University of Nottingham. A set series of questions will  
4 be used for the first two interviews, but may be adapted based on the findings of these  
5 interviews.  
6

## 7 **Compliance**

8 We do not expect any compliance issues.  
9

## 10 **Criteria for terminating the study**

11 None.  
12

## 13 **ANALYSES**

### 14 **Methods**

15  
16 A semi-structured interview guide (see attached document) has been developed around topic  
17 themes from existing literature and in our scoping review (see Box 1), however, this is flexible  
18 to allow unanticipated themes to emerge. Participants recruited will be asked in the initial email  
19 with the participant information sheet and consent form, to make anonymised notes on a  
20 maximum of three cases of cellulitis they have managed, to discuss in the interview. They will  
21 be asked to make notes on the following topics: signs, symptoms, tests used, challenges  
22 encountered with making a diagnosis, learning points for future cases.  
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#### 30 **Box 1: Interview topic themes**

31 Themes 1: Clinical features of suspected cellulitis

32 Themes 2: Experiences of diagnosis  
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37 All interviews will be audio-recorded and transcribed verbatim, with participant numbers  
38 assigned to avoid any personal identifiers.  
39

40 All idiosyncratic features that add no meaning to the transcript will be removed. The cleaned  
41 transcripts will then be formatted for read-in compatibility with the data management software,  
42 password protected and stored on the secure server at the University of Nottingham.  
43

44 The data transcripts will be organised using the qualitative software package QSR NVivo 12.  
45 The data will then be handled following the conventions of framework analysis<sup>8</sup>. A broad  
46 analytic framework based upon the topic themes and interview questions will be constructed,  
47 and subsequently refined by coding a small number of transcripts<sup>9</sup>. Coding will be done by  
48 one researcher (MP) and validated by an independent reviewer (JK, KT or PL). All other data  
49 will be charted to the refined framework. Once charting has been completed, thematic matrices  
50 can be interpreted and summaries of each theme / sub-theme produced (Appendix 1).  
51 Comparisons will be made between the data from different specialities.  
52  
53

## 54 **Data storage**

Copies of the audio data files will be uploaded to a secure electronic platform to allow data transfer between the study team and the transcriber. Once the transcripts have been generated, uploaded to the platform, and retrieved by the study team, the audio files will be deleted from the platform. All raw audio data files and transcripts will be encrypted, password protected and stored on a secure server at the University of Nottingham.

### **Sample size and justification**

We approximate that 20 participants will be included as a purposive sample. This number has been chosen because it is feasible to include within the limits of study funding and time. We aim to recruit both doctors and nurses in specialties of general practice, dermatology and either the emergency department or acute medicine, as all these three specialties manage cellulitis frequently. All participants need to have at least two years of clinical experience, as this will include HCPs who have specialist registration and will likely have more clinical experience of cellulitis.

We aim to include an equal number of men and women, with varying number of years of clinical experience as their clinical experiences will change with time. With regards to the GPs and emergency care staff, we want to include both those with more specialist dermatology or infection expertise, and those without.

### **ADVERSE EVENTS**

The occurrence of an adverse event as a result of participation within this study is not expected and no adverse event data will be collected.

### **ETHICAL AND REGULATORY ASPECTS**

If confidential information, defined as information that may identify an individual or place, is shared during the interview, then this will be omitted from the saved copy of the transcript.

The researchers will not impart any medical judgements or opinions. However, if information is shared that may have affected patient safety, then this will be discussed with the CI and escalated as required.

### **ETHICS COMMITTEE AND REGULATORY APPROVALS**

The study will not be initiated before the protocol, consent forms and participant information sheets have received approval / favourable opinion from the Research Ethics Committee (REC), the respective National Health Service (NHS) or other healthcare provider's Research & Development (R&D) department. Should a protocol amendment be made that requires REC approval, the changes in the protocol will not be instituted until the amendment and revised informed consent forms and participant information sheets (if appropriate) have been reviewed and received approval / favourable opinion from the REC and R&D departments. A protocol amendment intended to eliminate an apparent immediate hazard to participants may be implemented immediately providing that the REC are notified as soon as possible and an approval is requested. Minor protocol amendments only for logistical or administrative changes may be implemented immediately; and the REC will be informed.

1  
2 The study will be conducted in accordance with the ethical principles that have their origin in  
3 the Declaration of Helsinki, 1996; the principles of Good Clinical Practice, and the UK Policy  
4 Framework for Health and Social Care Research 2017.  
5  
6  
7

## 8 **INFORMED CONSENT AND PARTICIPANT INFORMATION**

9 The process for obtaining participant informed consent will be in accordance with the REC  
10 guidance, and Good Clinical Practice (GCP) and any other regulatory requirements that might  
11 be introduced. The investigator and the participant shall both sign and date the Consent Form,  
12 for face-to face interviews, before the person can participate in the study. Recorded verbal  
13 consent will be taken for telephone interviews before participation and the Consent Form  
14 posted after the interview to sign and return to the research team.  
15

16 The participant will receive a copy of the signed and dated forms and the original will be  
17 retained in the Study records.  
18

## 19 **RECORDS**

### 20 **Case report form**

21 Each participant will be assigned a participant number. There will be one case report form  
22 (CRF), keeping a record of all: participant's name, date of birth and participant study number.  
23 This form will be stored in a secure file that only the researchers can access. In line with the  
24 UoN data storage procedures, data will be stored for at least 7 years.  
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27 This CRF will be treated as confidential documents and held securely in accordance with  
28 regulations. The CRF shall be restricted to those personnel approved by the CI and recorded  
29 as such in the study records.  
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31

32 All paper forms shall be filled in using black ballpoint pen. Errors shall be lined out but not  
33 obliterated by using correction fluid and the correction inserted, initialled and dated.  
34  
35

### 36 **Source documents**

37 Source documents shall be filed at the investigator's site and may include but are not limited  
38 to, consent forms, study records, interview transcriptions and audio records. Only study staff  
39 shall have access to study documentation other than the regulatory requirements listed below.  
40  
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### 42 **Direct access to source data / documents**

43 All source documents shall be made available at all times for review by the CI, Sponsor's  
44 designee and inspection by relevant regulatory authorities.  
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## 50 **DATA PROTECTION**

51 All study staff and investigators will endeavour to protect the rights of the study's participants  
52 to privacy and informed consent, and will adhere to the current UK General Data Protection  
53 regulation (GDPR). The CRF will only collect the minimum required information for the  
54 purposes of the study. The CRF will be held securely, in a locked room, or locked cupboard or  
55 cabinet. Access to the information will be limited to the study staff and investigators and any  
56 relevant regulatory authorities. Computer held data including the study database will be held  
57

1  
2 securely and password protected. All data will be stored on a secure dedicated web server.  
3 Access will be restricted by user identifiers and passwords (encrypted using a one way  
4 encryption method).  
5

6 Electronic data will be backed up every 24 hours to both local and remote media in encrypted  
7 format.  
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9 Any medical information provided will be kept confidential.  
10

## 11 **QUALITY ASSURANCE & AUDIT**

  
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### 13 **INSURANCE AND INDEMNITY**

14 Insurance and indemnity for clinical study participants and study staff is covered within the  
15 NHS Indemnity Arrangements for clinical negligence claims in the NHS, issued under cover of  
16 HSG (96)48. There are no special compensation arrangements, but study participants may  
17 have recourse through the NHS complaints procedures.  
18

19 The University of Nottingham as research Sponsor indemnifies its staff, research  
20 participants and research protocols with both public liability insurance and clinical trials  
21 insurance. These policies include provision for indemnity in the event of a successful litigious  
22 claim for proven non-negligent harm.  
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### 26 **STUDY CONDUCT**

27 Study conduct may be subject to systems audit for inclusion of essential documents;  
28 permissions to conduct the study; CVs of study staff and training received; local document  
29 control procedures; consent procedures and recruitment logs; adherence to procedures  
30 defined in the protocol (e.g. inclusion / exclusion criteria, timeliness of visits); accountability of  
31 study materials and equipment calibration logs.  
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### 35 **STUDY DATA**

36 Monitoring of study data shall include confirmation of informed consent; data storage and data  
37 transfer procedures; local quality control checks and procedures, back-up and disaster  
38 recovery of any local databases.  
39

40 Study data and evidence of monitoring and systems audits will be made available for inspection  
41 by the ethics committee as required.  
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### 45 **RECORD RETENTION AND ARCHIVING**

46 In compliance with the University of Nottingham Code of Research Conduct and Research  
47 Ethics, the CI will maintain all records and documents regarding the conduct of the study.  
48 These will be retained for at least 7 years or for longer if required. If the responsible investigator  
49 is no longer able to maintain the study records, a second person will be nominated to take over  
50 this responsibility.  
51

52 The study documents held by the CI on behalf of the Sponsor shall be finally archived at secure  
53 archive facilities at the University of Nottingham. This archive shall include all anonymised  
54 transcripts, study databases and associated meta-data encryption codes.  
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## DISCONTINUATION OF THE STUDY BY THE SPONSOR

The Sponsor reserves the right to discontinue this study at any time for failure to meet expected enrolment goals, for safety or any other administrative reasons. The Sponsor shall take advice as appropriate in making this decision.

## STATEMENT OF CONFIDENTIALITY

Individual participant medical or personal information obtained as a result of this study are considered confidential and disclosure to third parties is prohibited with the exceptions noted above.

If information is disclosed during the study that could pose a risk of harm to the participant or others, the researcher will discuss this with the CI and where appropriate report accordingly.

Data generated as a result of this study will be available for inspection on request by the participating physicians, the University of Nottingham representatives, the REC, local R&D Departments and the regulatory authorities.

## PUBLICATION AND DISSEMINATION POLICY

The study results will be published in a peer reviewed academic journal and presented at conferences. All the participants will be sent the results, unless they request not to receive them. The manuscript will follow the Standards for Reporting Qualitative Research (SRQR) recommendations.

Participants will not be identifiable in the dissemination of results.

## USER AND PUBLIC INVOLVEMENT

This study was developed from priorities in cellulitis research identified by patients at the cellulitis PSP. A patient with cellulitis, as a collaborator, has helped in the design of this protocol.

The results will also be discussed at the annual CEBD patient panel, with patients with various skin diseases present, including cellulitis.

## STUDY FINANCES

### Funding source

Funding from the RCGP Practitioners allowance will be sought, providing a maximum of £2000. The application form requires the sponsor to agree to act as a research sponsor and so will be submitted after this ethics application has been submitted.

### Participant stipends and payments

Participants will be offered a £20 amazon inconvenience voucher, or a £20 donation to charity on their behalf, to participate in the study. This will ensure a gesture of gratitude, without influencing the participant response.

Page 16 of 20

Diagnosing lower limb cellulitis  
- Final Version 1.0 Date 31.10.2018

This protocol is confidential and the property of the University of Nottingham. No part of it may be transmitted, reproduced, published, or used by others persons without prior written authorisation from the University of Nottingham <http://bmjopen.bmj.com/site/about/guidelines.xhtml>

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3 Travel expenses will be provided for participants to attend a face-to-face interview.  
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For peer review only

**SIGNATURE PAGES**

Signatories to Protocol:

**Chief Investigator:** (name) \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

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## Appendix 1



Themes and sub-themes we believe may be described in the study

Key themes	Sub-themes
Diagnosis	Symptoms asked Signs sought Tests done Decision making aids
Challenges	Differential diagnoses Time as a factor Patient expectation Previous experiences Knowledge gap Confidence in making a diagnosis

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# BMJ Open

## An interview study to determine the experiences of cellulitis diagnosis amongst health care professionals in the UK.

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2019-034692.R1
Article Type:	Original research
Date Submitted by the Author:	23-Mar-2020
Complete List of Authors:	Patel, Mitesh; University of Nottingham, ; Lee, Siang Ing; University of Nottingham, Nottingham, UK, Division of Primary Care & National Institute for Health Research, School of Medicine, Levell, Nick; Norfolk and Norwich University Hospital NHS Foundation Trust, Dermatology Smart, Peter; University of Nottingham, Nottingham, UK Kai, Joe; University of Nottingham, Nottingham, UK Thomas, Kim; University of Nottingham, Centre of Evidence Based Dermatology Leighton, Paul; University of Nottingham, Centre of Evidence Based Dermatology
<b>Primary Subject Heading</b>:	Dermatology
Secondary Subject Heading:	Infectious diseases, Qualitative research
Keywords:	DERMATOLOGY, Adult dermatology < DERMATOLOGY, Infectious diseases & infestations < DERMATOLOGY, QUALITATIVE RESEARCH

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Manuscripts



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1 **Title:** An interview study to determine the experiences of cellulitis diagnosis amongst health care  
2 professionals in the UK.

3 **Running head:** Cellulitis diagnosis by health care professionals

4 **Word count:** 3262

5 **Table count:** 3

6 **Figure count:** 1

7 **Supplementary materials:** Figure 1, Table 1

8 **Authors:** M Patel, <sup>1,2</sup> S I Lee, <sup>1</sup> NJ Levell, <sup>3</sup> P Smart, <sup>4</sup> J Kai, <sup>1</sup> KS Thomas, <sup>2</sup> P Leighton, <sup>2</sup>

9 <sup>1</sup> Division of Primary Care & National Institute for Health Research, School of Medicine, University  
10 of Nottingham, Nottingham, UK

11 <sup>2</sup> Centre of Evidence Based Dermatology, University of Nottingham, Nottingham, UK

12 <sup>3</sup> Dermatology Department, Norfolk and Norwich University Hospital NHS Trust, UK

13 <sup>4</sup> Patient representative, Centre of Evidence Based Dermatology, University of Nottingham,  
14 Nottingham, UK

15  
16 **ORCID ID:** M Patel (0000-0003-3975-4689), S I Lee (0000-0002-2332-5452), NJ Levell (0000-  
17 0003-3393-8305), J Kai (0000-0001-9040-9384), KS Thomas (0000-0001-7785-7465), P  
18 Leighton (0000-0001-5208-0274),

19 **Corresponding author:** Mitesh Patel, Division of Primary Care, School of Medicine, University of  
20 Nottingham, Nottingham, UK, Email: mpatel59@doctors.org.uk

21  
22 **Funding sources:** This study was supported by the Scientific Foundation Board of the Royal  
23 College of General Practitioners (grant SFB 2018 – 31).

24  
25 **Study registration:** Centre of Evidence Based Dermatology website -  
26 [https://www.nottingham.ac.uk/research/groups/cebd/documents/researchdocs/protocol-](https://www.nottingham.ac.uk/research/groups/cebd/documents/researchdocs/protocol-diagnosing-lower-limb-cellulitis-health-care-professionals.pdf)  
27 [diagnosing-lower-limb-cellulitis-health-care-professionals.pdf](https://www.nottingham.ac.uk/research/groups/cebd/documents/researchdocs/protocol-diagnosing-lower-limb-cellulitis-health-care-professionals.pdf)

28  
29 **Data sharing:** No additional data available



## Abstract

**Objectives:** To explore health care professionals (HCPs) experiences and challenges in diagnosing suspected lower limb cellulitis.

**Setting:** UK nationwide.

**Participants:** 20 qualified HCPs, who had a minimum of two years clinical experience as a HCP in the national health service and had managed a clinical case of suspected cellulitis of the lower limb in the UK.

HCPs were recruited from departments of dermatology (including a specialist cellulitis clinic), general practice, tissue viability, lymphoedema services, general surgery, emergency care and acute medicine.

Purposive sampling was employed to ensure that participants included consultant doctors, trainee doctors and nurses across the specialties listed above. Participants were recruited through: national networks,

54 HCPs who contributed to the cellulitis priority setting partnership (PSP), UK Dermatology Clinical Trials  
55 Network, snowball sampling where participants helped recruit other participants, personal networks of the  
56 authors.

57 **Primary and secondary outcomes:** Primary outcome was to describe the key clinical features which inform  
58 the diagnosis of lower limb cellulitis. Secondary outcome was to explore the difficulties in making a  
59 diagnosis of lower limb cellulitis

60 **Results:** The presentation of lower limb cellulitis changes as the episode runs its course. Therefore, different  
61 specialties see clinical features at varying stages of cellulitis. Clinical experience is essential to being  
62 confident in making a diagnosis, but even amongst experienced HCPs, there were differences in the clinical  
63 rationale of diagnosis. A group of core clinical features were suggested, many of which overlapped with  
64 alternative diagnoses. This emphasises how the diagnosis is challenging, with objective aids and a greater  
65 understanding of the mimics of cellulitis required.

66 **Conclusion:** Cellulitis is a complex diagnosis and has a variable clinical presentation at different stages.  
67 Although cellulitis is a common diagnosis to make, HCPs need to be mindful of alternative diagnoses.

68 **Keywords:** lower limb, cellulitis, diagnosis, health care professionals

70 **Article summary**

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3 71 Strengths and limitations of this study  
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- 7 72 • Participants were included nationally around the UK, across various specialities that  
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10 73 commonly diagnose cellulitis, with both nurses and doctors of varying clinical experience.  
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13 74 • A small sample size was recruited, which limits the generalisability of our findings.  
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16 75 • Those with a specialist interest in dermatology were more likely to be recruited, which may  
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19 76 not be representative of the views of all health care professionals.  
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22 77 • Some participants were unable to fully describe their clinical rationale behind diagnostic  
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25 78 decisions during the interview.  
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28 79 • Interviewees may not have fully shared the details of cases that were misdiagnosed or  
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31 80 where diagnoses were delayed due to social desirability bias or fear of litigation.  
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## 90 Introduction

91 Cellulitis is a frequent presentation in both the community and secondary care, with 60% of  
92 presentations affecting the lower limbs.<sup>1</sup> However, the diagnosis of cellulitis can be challenging,  
93 with up to a third of suspected lower limb cellulitis cases being later diagnosed as other  
94 diagnoses.<sup>2</sup> This results in avoidable hospital admissions and unnecessary antibiotic prescribing  
95 <sup>3</sup> and is further compounded by the lack of validated diagnostic criteria or tools for cellulitis.<sup>4</sup>

96 A UK cellulitis research priority setting partnership (PSP) determined that improving health care  
97 professionals' (HCPs) diagnostic accuracy is a key priority for future cellulitis research.<sup>5</sup> An  
98 interview study of people with recurrent cellulitis and lymphoedema suggested that patients often  
99 experience difficulties in obtaining a speedy and accurate diagnosis.<sup>6</sup>

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3 100 The aims of this interview study were to explore the HCP experiences and challenges faced in  
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7 101 diagnosing suspected lower limb cellulitis.  
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48 **Methods**

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53 112 **Protocol registration and Ethics**  
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3 113 The final protocol was registered on the Centre of Evidence Based Dermatology (CEBD) website  
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7 114 (9 May 2019). Ethical approval was granted by the Health Research Authority and Health and  
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10 115 Care Research Wales (19/HRA/0485) (30 November 2018). Verbal and written consent was  
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13 116 obtained from each participant.  
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### 17 117 **Patient and public involvement**

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21 118 The research question was developed from research priorities in the cellulitis PSP, involving  
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24 119 patients. A patient representative helped design this study and is a co-author. On publication,  
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27 120 participants will be sent the final manuscript.  
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### 31 121 **Eligibility criteria**

### 35 122 **Selection of participants**

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39 123 Participants were qualified HCPs, who had a minimum of two years clinical experience as a HCP  
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42 124 in the national health service (NHS) and had managed a clinical case of suspected cellulitis of the  
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45 125 lower limb in the UK. Two year's experience was the minimum requirement as then HCP's will  
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48 126 have gained adequate exposure to cellulitis cases. HCPs were recruited from departments of  
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51 127 dermatology (including a specialist cellulitis clinic), general practice, tissue viability, lymphoedema  
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55 128 services, general surgery, emergency care and acute medicine.  
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3 129 Purposive sampling was employed to ensure that participants included consultant doctors, trainee  
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6 130 doctors and nurses across the specialties listed above. Participants were recruited through:

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10 131 • National networks  
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13 132 • HCPs who contributed to the cellulitis PSP  
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16 133 • UK Dermatology Clinical Trials Network  
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19 134 • Snowball sampling where participants helped recruit other participants  
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22 135 • Personal networks of the authors  
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26 136 Potential participants were approached and recruited by email. Data collection and analysis were  
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29 137 undertaken concurrently and sampling ceased when thematic saturation had been achieved (i.e.  
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32 138 new interviews generated no new insights).<sup>7</sup>  
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### 35 139 **Researcher characteristics**

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38 140 Interviews were conducted by MP (male), and coded and analysed by MP and SIL (female) (both  
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41 141 general practitioner (GP) trainees who had managed clinical cases of cellulitis previously). Both  
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45 142 MP and SIL attended qualitative methodology training courses. The broader research group  
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48 143 included experienced clinical-academics (JK (academic GP) and NL (clinical professor of  
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51 144 dermatology), a patient representative (PS) and senior qualitative experts (JK and PL). Three  
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54 145 participants had clinical interactions with the interviewer in the past, but not regarding cellulitis.  
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4 146 **Interview setting**  
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7 147 Each participant took part in a single, semi-structured, qualitative interview. Two interviews were  
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10 148 face to face, with the remaining via telephone. Written consent was gained from participants, with  
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13 149 additional verbal consent gained before the interview. All participants received a £20  
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17 150 reimbursement voucher or donated this fee to the British Skin Foundation charity.  
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20 151 **Data collection**  
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24 152 Prior to the interview, participants were asked to reflect upon their most recent experiences of  
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27 153 making a cellulitis diagnosis, focusing on the typical presentations, challenging cases and  
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31 154 differential diagnoses.  
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35 155 A topic guide, informed by a prior systematic review and interview study,<sup>8</sup> was used to structure  
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38 156 the interview (Supplementary materials, Figure 1). However, participants were urged to propose  
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41 157 and/or expand on topics which they felt were relevant to their experience of diagnosis. New topics  
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45 158 were then added to the topic guide for subsequent interviews.  
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48 159 **Data processing**  
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3 160 Interviews were audio-recorded and transcribed. Transcripts were checked (by MP) and data  
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7 161 managed using QSR NVivo 12 software.  
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## 10 11 162 **Data analysis** 12

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15 163 Analysis was inductive, searching for themes in the data. A structured, systematic, multi-stage  
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18 164 approach to thematic analysis was followed.<sup>9</sup> Coders immersed themselves in the data, by  
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21 165 reading the data set before coding. Data were coded manually by MP, with SIL also independently  
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24 166 coding a third of the transcripts. A list of each code, with a brief description was then used to  
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27 167 group the codes into theme-piles. Themes were defined and refined, with sub-themes also  
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31 168 developed.  
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35 169 Uncertainties in coding and thematic organisation were resolved in discussion with the other  
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38 170 authors. Data collection and analysis was concurrent. The final codebook was agreed by all  
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41 171 authors and is presented in Figure 1. The interviewer kept a reflexive research diary, logging  
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44 172 intuitive thoughts and immediate reflections after each interview. These reflections, as well as  
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47 173 queries around data collection, handling and interpretation were then discussed at regular  
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51 174 research meetings.  
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## 179 Results

180 Twenty HCPs were interviewed (Table 1). Interviews were conducted between 19 March and 11  
 21 June 2019, with a mean duration of 29 minutes.

182 **Table 1: Characteristics of the participants**

Participant	Ethnicity	Clinical role	Number of times they have diagnosed cellulitis	Time since they last diagnosed cellulitis
1	British Asian	GP	>50	One week ago
2	British Caucasian	Acute medicine/infectious disease consultant	>50	One week ago
3	Irish Caucasian	GP	>50	Three weeks ago
4	British Caucasian	Acute medicine consultant	>50	Last four weeks
5	British Caucasian	Acute medicine consultant	>50	One week ago

6	British Caucasian	Tissue viability nurse	10-50	Less than one week
7	British Caucasian	Lymphoedema specialist nurse	>50	One week ago
8	British Asian	Emergency medicine consultant	>50	Less than one week
9	British Asian	Dermatology consultant	10-50	Four weeks ago
10	British Caucasian	District nurse	>50	Last three months
11	Black	GP trainee	10-50	Less than one week
12	British Asian	GP locum	10-50	Two weeks ago
13	British Asian	GP out of hours	>50	Two weeks ago
14	British Caucasian	Dermatology specialist nurse	>50	Last three months
15	British Caucasian	Dermatology consultant	10-50	Last 12 months
16	Mixed	Surgical trainee	10-50	Last four weeks
17	British Caucasian	Community advanced nurse practitioner	>50	Less than one week
18	British Caucasian	Dermatology trainee	>50	Four weeks ago
19	British Caucasian	Emergency medicine consultant	>50	Last three months
20	British Caucasian	Dermatology consultant	>50	Less than one week

183

184 **Main findings**

Themes	Sub-themes	Codes
The patient	The typical patient and	<ul style="list-style-type: none"> <li>• Typical cellulitis presentations</li> </ul>

185 Four key themes were identified: 1) The patient presentation; 2) Challenges leading to diagnostic  
 186 uncertainty; 3) Strategies to improve diagnosis; 4) The need for an objective diagnostic aid, with  
 187 further classification into sub-themes. How the codes mapped onto the overarching themes are  
 188 shown in Table 2. Quotes from participants are shown in Supplementary Table 1.

198 **Table 2: How the codes mapped onto themes**

<b>presentation</b>	risk factors	<ul style="list-style-type: none"> <li>• Factors that increase the likelihood of cellulitis diagnosis</li> </ul>
	Confidence in diagnosis	<ul style="list-style-type: none"> <li>• Most suitable HCP to diagnose cellulitis</li> <li>•</li> </ul>
		<ul style="list-style-type: none"> <li>• Experience guides diagnosis</li> </ul>
	Cases of misdiagnoses	<ul style="list-style-type: none"> <li>• Missed/delayed diagnosis of cellulitis (final diagnosis)</li> </ul>
		<ul style="list-style-type: none"> <li>• Missed/delayed diagnosis of cellulitis (initial diagnosis)</li> </ul>
Differential diagnoses	<ul style="list-style-type: none"> <li>• List of alternative diagnosis</li> </ul>	
<b>Challenges leading to diagnostic uncertainty</b>	Continuum of clinical features	<ul style="list-style-type: none"> <li>• Changes in clinical presentation</li> </ul>
	A subjective diagnosis	<ul style="list-style-type: none"> <li>• Reasons why cellulitis diagnosis is challenging</li> </ul>
	Community challenges	<ul style="list-style-type: none"> <li>• Seeing patients part way through assessment and management</li> </ul>
		<ul style="list-style-type: none"> <li>• Follow up of patients</li> </ul>
	The role of 'defensive' medicine	<ul style="list-style-type: none"> <li>• Sepsis as a concern</li> <li>• Medico legal issues as a factor</li> </ul>
		<ul style="list-style-type: none"> <li>• Fear of missing more serious differentials</li> </ul>
Patient specific factors	<ul style="list-style-type: none"> <li>• Other factors influencing diagnosis</li> </ul>	
<b>Strategies to improve diagnosis</b>	Using time as a guide	<ul style="list-style-type: none"> <li>• Time and safety netting approach</li> <li>•</li> </ul>
	Trial of treatment	<ul style="list-style-type: none"> <li>• Trial of treatment guides diagnosis</li> <li>•</li> </ul>
	Biochemical investigations	<ul style="list-style-type: none"> <li>• Investigations to aid diagnosis</li> </ul>

	Seeking advice	<ul style="list-style-type: none"> <li>• Discussing diagnosis with colleagues</li> </ul>
	Further education	<ul style="list-style-type: none"> <li>• Suggestions on what may improve diagnosis</li> </ul>
<b>The need for an objective diagnostic aid</b>	A diagnostic algorithm	<ul style="list-style-type: none"> <li>• Views on diagnostic aids for HCP</li> </ul>
	Indices for an algorithm	<ul style="list-style-type: none"> <li>• Clinical features to include in diagnostic algorithm</li> </ul>

199

## 200 **Diagnosis of cellulitis**

### 201 *The typical patient and risk factors*

202 In general practice, the typical patient described by participants included older adults with co-  
 203 morbidities; concerns of possible cellulitis cases were often raised by district nursing colleagues.

204 Emergency care and acute services described people who presented with features of systemic  
 205 compromise. Both infectious disease and general surgery services often managed intravenous  
 206 drug users who were at risk of deeper infection.

207 Factors that HCPs stated increased the likelihood of cellulitis were: features of systemic upset  
 208 including fever, malaise, rigors; co-existing injury or infection such as tinea, superficial ulceration,  
 209 previous history of cellulitis, previous history of dermatological conditions such as eczema,  
 210 diabetes, immunosuppressive medications and those with no fixed abode with social and health

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3 211 risks. Bilateral symptoms were commonly described by participants as a factor increasing the  
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6 212 likelihood of chronic, systemic pathologies rather than cellulitis.  
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10 213 *Confidence in diagnosis*  
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14 214 One dermatologist explained how being more aware of the differential diagnoses made them  
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16  
17 215 more likely to accurately diagnose cellulitis, especially compared to junior colleagues . Generally,  
18  
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21 216 HCPs with more clinical experience felt more confident with diagnosis, as they appreciated the  
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23  
24 217 presentation with more observed cases.  
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27 218 A dermatology trainee felt seeing less cellulitis cases during their training compared to their senior  
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31 219 colleagues historically and therefore not getting as much exposure hindered accurate diagnosis.  
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34 220 *Cases of misdiagnoses*  
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36

37 221 Trauma related skin changes was frequently an initial misdiagnosis in the emergency department.  
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39  
40 222 When discussing cases of uncertainty, where cellulitis was the initial suspected diagnosis, one  
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44 223 GP described a case of venous eczema which was managed with repeated antibiotics. Chronic  
45  
46  
47 224 rashes were frequently seen by dermatology and infectious disease discussed lymphoma cases  
48  
49  
50 225 initially referred as cellulitis.  
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226 The importance of a correct diagnoses is key, as two participants discussed the possibility of  
 227 prophylactic antibiotics for patients with recurrent cellulitis. A dermatology consultant explained  
 228 how misdiagnosis can result in inappropriate and costly admissions to the ward.

### 229 *Differential diagnoses*

230 A frequent diagnosis of uncertainty for primary and emergency care was DVT, as the clinical  
 231 features of cellulitis can overlap. Common differential diagnoses discussed by participants, which  
 232 they observed in their clinical practice, with discriminating features from cellulitis that they  
 233 described, are shown in Table 3.

234 **Table 3:** Differential diagnoses of lower limb cellulitis discussed by participants

Differential diagnoses	Key differentiating factors from cellulitis
Chronic heart failure causing oedema	Chronic, bilateral, lack of mobility, breathless, cardiac history (P1,GP;P14,dermatology specialist nurse)
Venous eczema	Usually chronic with hemosiderin scaling, itching, crusting, likely bilateral, possibly eczema elsewhere on body, less well defined, (P3,GP;P15, dermatology consultant)



Thrombophlebitis	Tender, localised, hard, lumpy rash around an often-thickened vein (P3,GP;P5,acute medicine consultant;P12,GP locum)
Erythema nodosum	Multiple, discrete swellings (P13,GP out of hours)
Deep vein thrombosis	Pain is usually deep in calf rather than superficial, less sharply demarcated and less intense erythema, diffuse swelling of limb, can be young, can be intravenous drug users, high DVT wells score, fewer systemic features (P2,infectious disease consultant;P12,GP locum;P13,GP out of hours)
Lymphoedema	Chronic, bilateral, usually less painful, thickened warty skin in the long-term, normal inflammatory markers (P9,dermatology consultant;P18,dermatology trainee)
Allergic reaction to insect bites	Central puncture mark, itch, when acute, developing lichenified erythema when chronic (P2,infectious disease consultant)
Lipodermatosclerosis	Often bilateral, systemically well, tight non tender skin with inverted champagne bottle appearance (P4,acute medicine consultant; P20,dermatology consultant)
Necrotising fasciitis	Crepitus, rapidly spreading, septic, very tender (P5,acute medicine consultant; P16, surgical trainee)
Wound infection	Local to the wound, covers small area, yellow exudate, strong odour (P10,district nurse; P16,surgical trainee)

Baker's cyst	Unilateral popliteal swelling, suddenly more tender on rupture (P15,dermatology consultant)
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## 236 Challenges leading to diagnostic uncertainty

### 237 *The continuum of clinical features*

238 Participants described how the presentation of lower limb cellulitis changed as the episode ran its  
 239 course. This was influenced by when patients seek clinical review and meant that different  
 240 specialties observed clinical features at varying stages of cellulitis.

241 In dermatology services, presentations were seen later in the episode. However, partial treatment  
 242 and response did make the diagnosis challenging as the initial typical features of cellulitis may  
 243 then vary. However, seeing patients later in the journey allowed dermatologists to appreciate the  
 244 progression of clinical features. Importantly for dermatologists, other more serious pathologies  
 245 such as a deep vein thrombosis (DVT) had often been ruled out.

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### 247 *A subjective diagnosis*

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3 248 One GP explained how there is no specific test that can aid diagnosis, thus subjective assessment  
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7 249 can lead to different diagnoses. She added how this is further influenced by previous experiences,  
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10 250 including how long and where HCPs have trained.

### 13 251 *Community challenges*

16 252 In the community, additional challenges for GPs were not being familiar with the patient's  
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20 253 background history, seeing a patient for the first time, or taking over care part way through the  
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23 254 patient journey. Working as a locum doctor with a lack of follow up available, often led to treatment  
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26 255 when unsure of the diagnosis. Limited resources to see patients, such as not being able to  
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29 256 conduct an urgent home visit, also influenced diagnosis and subsequent management by GPs.

### 32 257 *The role of 'defensive' medicine*

36 258 HCPs in the community, emergency care and surgery were particularly wary of missing a more  
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39 259 serious diagnosis, which needed to be ruled out first, such as DVT and necrotising fasciitis (NF).  
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42 260 Many HCPs also mentioned '*sepsis*' when discussing clinical features and diagnosis. This may  
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45 261 be leading to an over diagnosis of cellulitis due to concerns of medico legal complaints of missing  
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48 262 an infection which could then get worse.

### 52 263 *Patient specific factors*

264 Participants found people with pigmented skin, lymphoedema and with nonspecific symptoms  
265 particularly difficult to diagnose in the acute setting. One nurse described another diagnostic  
266 challenge was when a patient presents with chronic skin changes or a recent episode of cellulitis  
267 with continuing signs.

## 268 **Strategies used to reduce uncertainty**

### 269 *Using time as a guide*

270 In cases where the HCP was not sure of the diagnosis, different strategies were employed. Using  
271 time to allow further clinical features to develop, with appropriate safety netting was a commonly  
272 used approach. This was easier when follow-up appointments were available in the community,  
273 but was also done in the acute setting . But follow-up in secondary care was difficult, often not  
274 done and can be a missed opportunity to learn from incorrect diagnoses previously.

### 275 *Trial of treatment*

276 Some HCPs started antibiotics for a suspected cellulitis and reviewed the response to help  
277 provide the diagnosis retrospectively. A major concern highlighted by one GP with this approach  
278 was antibiotic resistance and side effects. However, overall, there was a common understanding  
279 in primary care why this approach was taken in some instances.

### 280 *Biochemical investigations*

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4 281 In primary care, one doctor described how blood tests and cultures were rarely done to diagnose  
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7 282 cellulitis, as such patients would need to be seen in secondary care. Blood cultures were  
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10 283 requested by the infectious disease physician if it was an atypical infection, but a challenge  
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13 284 described by one dermatology consultant was that organisms are not isolated in the majority of  
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16 285 patients. Swabs were done for discharging wound infections, mainly by district nurses or prior to  
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19 286 discussion with microbiology, when see by dermatologists.

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23 287 An emergency physician and surgical trainee explained how blood tests and imaging such as x-  
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26 288 rays are important to check for osteomyelitis. The blood tests commonly requested by secondary  
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29 289 care HCPs were white cell count (WCC) and C-reactive protein (CRP) for infection with one  
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32 290 dermatologist stating how changes in blood test results were important when taking referrals for  
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35 291 suspected cellulitis. However, one challenge with interpreting blood tests was in the group partially  
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38 292 treated with antibiotics, who have improving blood tests but limited clinical response. A biomarker  
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41 293 or point of care test for cellulitis were suggested as investigations to aid diagnosis by one  
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44 294 dermatology consultant and one GP respectively.

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53 296 *Seeking advice*

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3 297 Another approach during uncertainty was to discuss with colleagues. In the community the nurse  
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7 298 may ask the GP to review and vice versa. In hospital, specialists in infectious disease,  
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10 299 dermatology, microbiology and general/plastic surgeons are most often contacted for review.  
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### 13 300 *Further education*

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16 301 Many HCPs mentioned teaching sessions to improve diagnosis, both at the undergraduate and  
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20 302 postgraduate level. One GP stated that real life clinical cases were felt to be important for  
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23 303 teaching, rather than focusing on pictures.  
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26  
27 304 A dermatology consultant suggested that a key area of education amongst HCPs was being  
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30 305 aware of differential diagnoses for the first point of access services. One trainee who worked in a  
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33 306 specialist cellulitis clinic found that seeing many cases helped improve her recognition of cellulitis.  
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### 37 307 **The need for an objective diagnostic aid**

#### 38 39 40 308 *A diagnostic algorithm*

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44 309 Many participants mentioned developing a diagnostic algorithm, similar to the Wells score for  
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47 310 DVT. A GP explained how this may also help GPs make a validated clinical decision when  
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50 311 colleagues such as district nurses are suspecting cellulitis and the patient cannot be seen quickly.  
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53 312 A dermatology nurse described how she often used checklists and how an algorithm would help  
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3 313 HCP's not to miss any clinical features. One dermatology consultant suggested that a diagnostic  
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7 314 checklist should be more of an educational tool to help rule out other differential diagnoses.  
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10 315 A dermatology trainee felt that the indices of a checklist would have to reflect how cellulitis  
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13 316 changes through the course of the episode. Other challenges described by participants, regarding  
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16 317 developing an algorithm were the number of alternative diagnoses, with features that often  
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19 318 overlapped with cellulitis and vague initial features. Another concern highlighted by a dermatology  
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22 319 consultant was that algorithms will miss patients who may present with atypical features, referred  
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25  
26 320 to as 'outliers'.

### 29 321 *Indices for an algorithm*

32 322 The key clinical features HCPs suggested to include in a diagnostic algorithm for lower limb  
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35 323 cellulitis were: unilateral, pain, erythema, warmth of limb, pyrexia, swelling, acute onset, trauma  
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38 324 to the limb, break in the skin, single area affected, clear demarcation, exudate, flu like malaise,  
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42 325 tracking rash, shiny, tenses skin, previous cellulitis, co-existing immunosuppression, co-existing  
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45 326 skin conditions, clinical observations for sepsis, negative Wells score and patient concern. No  
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48 327 HCP suggested blood tests were a priority in the algorithm, but a GP trainee suggested it could  
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51 328 be included in a modified algorithm in secondary care, similar to the CURB-65 score used for  
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55 329 pneumonia.

For peer review only

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## 347 Discussion

### 348 Summary

349 This study found that the presentation of lower limb cellulitis changes as the episode progresses,  
350 leading to variation in the clinical features, seen in different clinical settings. This may be reflected  
351 in the range of typical differential diagnoses that specialities discussed and has been described  
352 in literature.<sup>10</sup>

353 Clinical experience was described as an important factor in making a more accurate diagnosis.

354 Dermatologists have previously been suggested as the ideal HCP to diagnose cellulitis.<sup>11</sup>

355 However, the clinical reasoning behind a diagnosis were contradictory between some HCPs.

356 A core group of clinical features to diagnose cellulitis were suggested. But the challenge is that

357 these features can overlap with other pathologies, irrespective of how likely these are.<sup>12</sup> More

358 serious pathologies then need to be ruled out first, both for the safety of the patient and to avoid

359 medico-legal consequences.

360 Suggestions to improve the accuracy of diagnoses included developing a diagnostic algorithm

361 which could objectively help HCPs with different levels of experience.<sup>13</sup> The challenge with a

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3 362 diagnostic algorithm is that it would need to incorporate the various stages of a cellulitis episode  
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7 363 and therefore various versions of an algorithm might be required.  
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11 364 Importantly, having a greater understanding of the alternative diagnoses is required, especially  
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14 365 when the features are vague, atypical or not responding to antibiotic treatment. Educating both  
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16  
17 366 doctors and nurses, using real life clinical scenarios and a focus on differential diagnoses, was  
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19  
20 367 also discussed and may be an initial feasible approach to improve diagnostic accuracy. A visually  
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23 368 based computerized diagnostic decision support system, focusing on differential diagnoses, has  
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26 369 been shown to improve the diagnostic accuracy of cellulitis.<sup>14</sup>  
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### 30 **Strengths and limitations**

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34 371 A key strength of this study that participants were included nationally around the UK, across  
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38 372 various specialities that commonly diagnose cellulitis, with both nurses and doctors of varying  
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40  
41 373 clinical experience.  
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45 374 The major limitation of this study was the small sample size and therefore findings may not be  
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48 375 generalisable. This stems from the pragmatic design and feasibility of the study. The participants  
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51 376 in this study were mainly female doctors. This may not be representative of the workforce in non-  
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54 377 UK countries; therefore the transferability of our findings may be limited. In addition, as our  
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3 378 recruitment strategy is most likely to have targeted HCP's with an interest in dermatology, their  
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7 379 views may not be representative of other HCPs.  
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10 380 Furthermore, some participants were unable to fully describe their clinical rationale behind  
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13 381 diagnostic decisions during the interview. This may be because they have developed an intuitive,  
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16 382 pattern-recognition, approach in decision-making with experience. Such heuristic diagnostic  
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19 383 processes in dermatology are well documented.<sup>15</sup>  
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23 384 As the interviewer was a fellow clinician, interviewees may not have fully shared the details of  
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26 385 cases that were misdiagnosed or where diagnoses were delayed due to social desirability bias or  
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28  
29 386 fear of litigation. Clinical researcher bias was unavoidable, as the interviewer had clinical insight  
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33 387 into cellulitis. However, non-clinicians within the broader authorship group were also involved with  
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36 388 coding and analysis of the interviews.  
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39 389 Three participants were known to the interviewer, which can lead to response bias, however the  
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42 390 interviewer felt this also allowed an honest, open discussion.  
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#### 46 391 **Comparison with existing literature** 47 48

49 392 To our knowledge, this is the first interview study undertaken with health care professionals,  
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53 393 discussing their experiences of cellulitis diagnosis. Our findings on the clinical features of cellulitis,  
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3 394 differential diagnoses and also the need to be aware of mimics have been described in previous  
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7 395 review articles.<sup>10</sup> A previous review also described cases of misdiagnosis and emerging  
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10 396 approaches to improve diagnoses,<sup>8,16</sup> which were echoed in this study. The diagnostic challenges  
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13 397 of infection in primary care, due to atypical presentations and lack of diagnostic tests has  
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15  
16 398 previously been described.<sup>17</sup> Using treatments such as antibiotics as diagnostic aids and  
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19 399 discussing with colleagues when uncertain about a diagnosis are common strategies.<sup>18,19</sup>  
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23 400 Litigation and fear missing a diagnosis has also been well documented in literature.<sup>20</sup>  
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#### 26 401 **Implications for research and practice**

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30 402 This study has highlighted that HCPs need to be aware that cellulitis can present with different  
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33 403 features at various stages of the acute episode and need to consider the cellulitis mimics. With a  
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37 404 current shift in health care resulting in trained nurses now managing more acute presentations,<sup>21</sup>  
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40 405 upskilling nurses in cellulitis could be part of the solution.  
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44 406 Many HCPs felt confident in making an accurate diagnosis, often guided by experience and  
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47 407 intuition, but found it difficult to verbalise the key distinguishing features. This makes it difficult for  
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50 408 the clinical experience to be shared amongst other colleagues, especially less experienced or  
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53 409 junior HCPs. Acquiring this insight is important to improve diagnostic accuracy, which can prevent  
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3 410 avoidable antibiotic prescribing and hospital admissions. To overcome this, further qualitative  
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7 411 research is required to identify the clinical reasoning behind the expert process of making a  
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10 412 diagnosis, perhaps using clinical cases and pictures. This will form the basis of the proposed  
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13 413 solution of focused education and clinical features to be included in a diagnostic aid. The  
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16 414 challenge with further education for HCPs is that information needs to be accessible for everyone,  
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18  
19 415 whilst information overload can lead to a reduction in the quality of decisions.<sup>22</sup>  
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23 416 Some indices and risk factors for a diagnostic algorithm have been identified in this study and  
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26 417 previous studies,<sup>23</sup> as well as key distinguishing features from differential diagnosis, but these  
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29 418 need validating with larger studies and an expert consensus setting exercise.  
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## 38 420 **Conclusion**

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42 421 This interview study has shown that cellulitis is a complex diagnosis. Not only does the core  
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45 422 features overlap with other diagnoses, the presentation of cellulitis changes as the episode  
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48 423 progresses. Although cellulitis is a common diagnosis to make, and whilst further research in  
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51 424 developing diagnostic aids needs to be undertaken, simply being aware of the cellulitis mimics  
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53  
54 425 may help improve diagnostic accuracy.  
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56

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## 433 Competing interest

434 None declared

## 435 Author contributions

436 **M Patel** was involved with the design of the study, collection and analysis of data, drafting the  
437 manuscript and final approval of the manuscript.

438 **S I Lee** was involved with the design of the study, analysis of data, drafting the manuscript and  
439 final approval of the manuscript.

440 **NJ Levell** was involved with the design of the study, analysis of data, drafting the manuscript and  
441 final approval of the manuscript.

442 **P Smart** was involved with the design of the study, analysis of data, drafting the manuscript and  
443 final approval of the manuscript.

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3  
4 444 **J Kai** was involved with the design of the study, analysis of data, drafting the manuscript and final  
5 445 approval of the manuscript.  
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7 446 **KS Thomas** was involved with the design of the study, analysis of data, drafting the manuscript  
8 and final approval of the manuscript.  
9

10  
11 448 **P Leighton** was involved with the design of the study, analysis of data, drafting the manuscript  
12 and final approval of the manuscript.  
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37 513 **Figure 1: Standardised codebook used by two independent coders**

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19 533 **Supplementary Materials**

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23 534 **Figure 1: Topic guide used to structure the interview**

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27 535 **Table 1: Quotes provided by participants, mapped onto both the themes and sub-themes**

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## Codes used

- Trial of treatment guides diagnosis
- Discussing diagnosis with colleagues
- Time and safety netting approach
- Patients who self-diagnose and treat
- Approach when HCPs do not agree with patient self-diagnosis
- Patients involved with diagnosis with the HCP
- Typical cellulitis presentations
- Clinical features of cellulitis
- Factors that decrease the likelihood of cellulitis diagnosis
- Factors that increase the likelihood of cellulitis diagnosis
- Investigations to aid diagnosis
- Missed/delayed diagnosis of cellulitis (final diagnosis)
- Missed/delayed diagnosis of cellulitis (initial diagnosis)
- Patient finds it difficult to accept it is not cellulitis
- Reasons why cellulitis diagnosis is challenging
- Suggestions on what may improve diagnosis
- Views on diagnostic aids for HCP
- Views on diagnostic aids for patients
- Views on how well HCP make diagnosis
- Experience guides diagnosis
- Seeing patients part way through assessment and management
- Differential diagnoses
- Sepsis as a concern
- Medico legal issues as a factor
- Follow up of patients
- Most suitable HCP to diagnose cellulitis
- Fear of missing more serious differentials
- Clinical features to include in diagnostic algorithm
- Other factors influencing diagnosis

1 **If the participant has a recent case of cellulitis that they can discuss:**

2 **Can you tell me about a case of cellulitis that you diagnosed?**

3 Prompts:

- 4 • What thoughts go through your head when you are considering a diagnosis of cellulitis?
- 5 • What symptoms do you ask about? Local? General?
- 6 • What signs do you look for? Local? General?
- 7 • Are there any specific signs/symptoms you rely on to help?
- 8 • Did you do any tests?
- 9 • Did you seek advice from anyone else?
- 10 • Were you concerned that this may not be cellulitis?
- 11 • If you were concerned, why?
- 12 • Was there anything challenging about this case?
- 13 • How did you address these challenges?
- 14 • How confident were you that this was cellulitis on a 1-10 scale when you first saw the patient?
- 15 • Did the patient discuss any self-diagnoses?
- 16 • Did any external factors such as time influence your decision?
- 17 • Did the patient come back to see you again?
- 18 • Would you change your approach if the same case presented again?
- 19 • Is this a typical case you see?
- 20 • What are the main differential diagnoses you see?

24 Repeat the above for a maximum two cases that the participants may have for the interview (repeat twice only if the participant has no delayed/incorrect cases below).

27 **If the participant has a case where the diagnosis was delayed or incorrect (can be initially either seen by same health care professional or a colleague, but preferably the same person)**

29 Prompts:

- 30 • Did you see the patient on initial presentation or was it a colleague?
- 31 • If it was another colleague, what specialty did they work in?
- 32 • What symptoms did they present with?
- 33 • What signs did they have?
- 34 • What was the initial diagnosis? And why?
- 35 • Were any tests done?
- 36 • Did any external factors influence the decision for the initial diagnosis?
- 37 • When did they see you or another colleague again?
- 38 • If it was another colleague, what specialty did they work in?
- 39 • Did anything change with the signs/symptoms?
- 40 • What happened next?
- 41 • Do you know what the final diagnosis was?
- 42 • What were the reasons for the delay in the diagnosis?
- 43 • Why was it difficult to make an accurate diagnosis on first consultation?

44 **We want to establish if it is possible to determine a core group of features that can be used to help diagnose lower limb cellulitis**

46 Prompts:

- 47 • What symptoms are you asking about?

- Of these symptoms, which do you think are more suggestive of cellulitis?
- Are there any symptoms that make cellulitis less likely?
- Are there other features in the history which make cellulitis more/less likely? (prompt – other conditions, previous history, drugs, family history )
- What signs are you looking for?
- Of these signs, which do you think are more suggestive of cellulitis?
- Would you request any tests if it was available to you on the same day?
- If so what tests would these be?
- Are there any signs in a 'red leg' that would make cellulitis less likely as the diagnosis?
- Are there any signs in a red leg which would make cellulitis more likely as the diagnosis?
- How has your approach to diagnosing cellulitis changed after managing previous cases?
- If the patient has had previous cellulitis, does this influence your diagnosis?
- From your experience, what differential diagnoses do you think about?
- How do you distinguish cellulitis from these differential diagnoses?
- Specifically, how do you differentiate cellulitis from lymphoedema?
- Specifically, how do you differentiate cellulitis from venous eczema?
- Specifically, how do you differentiate cellulitis from infected venous eczema?
- Specifically, how do you differentiate cellulitis from lymphodermatosclerosis?
- Do you feel that a list of key diagnostic features of cellulitis would help when assessing patients?

**We want your views on some aspects of diagnosis that patients with recurrent cellulitis and lymphoedema have discussed**

- Patients felt that they were confident in making a self-diagnosis of cellulitis and valued greater trust in self-management at home with treatment. What are your thoughts on patients self-diagnosing?
- Would a photograph with a proforma taken and filled in by the patient and sent to you be helpful in managing patients with recurrent cellulitis?
- In the instance where you may not agree with the patients self-diagnosis of cellulitis, how would you manage the diagnosis?
- Do you feel that any further training or resources should be set up to help improve our diagnosis of cellulitis? For example as specialist cellulitis clinic to refer patients to?
- What are your thoughts on health care professionals having a guide such as checklist to help diagnosis?
- Do you think patients should have this checklist? If so why or why not?

Themes	Sub-themes	Participant quotes
The patient presentation	Confidence in diagnosis	<p><i>'I would say it is just experience [helping diagnosis], a lot of the juniors that come into A&amp;E have not seen that many cellulitis [cases]' (P19, emergency care consultant)</i></p> <p><i>'I probably thought more presentations were [cellulitis] as a junior doctor... I probably didn't really recognise that sort of stretched skin appearance.. I think that has come along as part of just experience over the years, so I probably diagnosed more cellulitis inappropriately as a more junior doctor' (P13, GP out of hours)</i></p>
	Cases of misdiagnoses	<p><i>'One of the nurse practitioners had seen ankle swelling and the patient thought it... he played some cricket two or three days ago and after one or two days the swelling appeared and she thought that it was just a sprain but next day he represented, I saw him and it looked more like cellulitis because it was quite red, localised area... on close examination I could see a couple of scratches around the ankle so that was maybe the source of cellulitis spreading on the leg' (P8, emergency care consultant)</i></p> <p><i>'We did see [patients] coming in with "oh this must be a resistant cellulitis", have got a swollen limb that might be a little bit red and it turns out to be some horrible form of lymphoma. You maybe get one or two of those every year where the assumption is that this must be cellulitis because they are really sick and it's a bit red and those can be quite difficult to tease out sometimes, simply because they are sick and the assumption is that it is an infection' (P2, infectious disease consultant)</i></p>



		<p><i>'Generally anything that is red and hot and on the legs is treated with antibiotics' (P1, GP)</i></p> <p><i>'There are too many chronic rashes that get referred [to dermatology] as cellulitis' (P18, dermatology trainee)</i></p>
	Differential diagnoses	<p><i>'One thing that is always a problem in leg swelling...it is difficult to ascertain between DVT and cellulitis' (P8, emergency care consultant)</i></p>
<b>Challenges leading to diagnostic uncertainty</b>	Continuum of clinical features	<p><i>'Usually the patient is already admitted ..... [the referring team] have tried [multiple antibiotics], but nothing is happening, "please can you come and tell us what is going on?" (P9, dermatology consultant)</i></p> <p><i>'There are varying ranges of erythema, from a little bit of light pinkness to rip roaring hot red, tender, well demarcated, unilateral; the classic sort of textbook stuff' (P18, dermatology trainee)</i></p> <p><i>' I learnt to appreciate much more that [cellulitis] is coming up, it is happening and that it is fading away. A lot of what happened when I was [junior], I was seeing [cellulitis] at the beginning and middle stages, trying to diagnose it, but in dermatology you're seeing it more at that other end of the spectrum..so I think there is a lot [to be] learnt about seeing that pattern developing and progressing and then resolving ' (P18, dermatology trainee)</i></p> <p><i>'Virtually every patient that I see...they have had their d-dimer and their duplex done so [DVT] is usually a diagnosis that has been excluded' (P20, dermatology consultant)</i></p>
	A subjective diagnosis	<p><i>'I think the fact that there is no specific diagnostic test... and two</i></p>

		<p><i>different people can look at [possible cellulitis] and come up with two different answers' (P1, GP)</i></p>
	<p>Community challenges</p>	<p><i>'You've not met the patient before and sometimes you're not going to be able to follow them up so you probably are more likely to give antibiotics' (P12, GP locum)</i></p> <p><i>'If you know the patient and you know that they have recurrent cellulitis, someone had seen it like a district nurse and it is Friday afternoon and you can't get out [for a visit].. you would make a judgement call (P1, GP)</i></p>
	<p>The role of 'defensive' medicine</p>	<p><i>'I think you would want to rule out DVT first because if you miss that then that is... a problem' (P1,GP; P16,surgical trainee)</i></p> <p><i>'We're so much more aware of things like sepsis... looking at any kind of signs of infection' (P10, district nurse)</i></p> <p><i>'We're all risk adverse aren't we? We would rather make sure we weren't sued because we had missed someone with an infection' (P2, infectious disease consultant)</i></p>
	<p>Patient specific factors</p>	<p><i>' One of these classical patients that comes in hasn't got a rash and hasn't necessarily got the features that I said of swelling, redness, rash and pain in the leg but they come in none specifically unwell and they may have described a bit of an ache in the leg or something like that but there is nothing else to go on examining the patient for signs, so I think those patients are much trickier' (P5, acute medicine consultant)</i></p> <p><i>'People with chronic red [legs], their legs are red most of the time.. the skin takes so long to settle, so they could have had cellulitis four weeks ago and it is</i></p>

		<i>still red'</i> (P17, advanced nurse practitioner)
<b>Strategies to improve diagnosis</b>	Using time as a guide	<i>'All you can really do is reassure the patient and say...I don't see any clear evidence of cellulitis but we will keep an eye on it.... you give safety net advice to the patients'</i> (P18, dermatology trainee)  <i>'So if they were well.. then I would bring them back to clinic the next day or two'</i> (P4, acute medicine consultant)
	Trial of treatment	<i>'Cellulitis...was the easiest thing to try and treat so I think that definitely pushed [me] to try some antibiotics and see if this is an infection'</i> (P11, GP trainee)  <i>'[My concerns with this approach] are antibiotic resistance and side effects...especially in older groups..I would say probably that is not the best approach'</i> (P3, GP)
	Biochemical investigations	<i>'If I am thinking about doing blood tests...it is unlikely that I am going to continue managing them in the community'</i> (P11, GP trainee)  <i>'[With cellulitis]....you expect a) it is unilateral, b) you want some inflammatory markers which are raised, at least a reasonable WCC and CRP and if it is normal it is not going to be cellulitis'</i> (P9, dermatology consultant)  <i>'I would never not diagnose somebody [with cellulitis] just because their inflammatory markers are normal'</i> (P5, acute medicine consultant)
	Further education	<i>'You very quickly just get entrenched in...your preferences for diagnoses and it is often good to refresh'</i> (P11, GP trainee)  <i>'I only did two weeks [of dermatology] as a medical student... but certainly increasing dermatology teaching at an earlier stage would make a massive difference'</i> (P13, GP).

		<p><i>'It is all very well seeing pictures but pictures aren't that helpful sometimes, it is how it feels sometimes that makes a difference and actually seeing it in the flesh is very different to seeing even good quality pictures, so I do think that clinical exposure [is important]' (P13, GP).</i></p> <p><i>'It is not something people will have put a lot of thought into, the differentials, and I think the focus needs to be on teaching the frontline staff' (P15, dermatology consultant).</i></p> <p><i>'Pattern recognition and [seeing] variation in the progression of the rash [are important]', thereby appreciating the 'life of rashes' (P18, dermatology trainee).</i></p>
<p><b>The need for an objective diagnostic aid</b></p>	<p>A diagnostic algorithm</p>	<p><i>'I think it can be helpful to have those objective measures [of an algorithm], if it was accepted and validated as a reasonable measure of cellulitis, I think I would actually use that' (P11, GP trainee).</i></p> <p><i>'[A checklist] could help people that weren't experienced or confident enough. To have a checklist as a learning tool is fabulous, it just gives you something to think about like "oh I hadn't thought about the smell, I hadn't thought about the heat"....and I use checklists all of the time' (P14, dermatology nurse).</i></p> <p><i>'For a diagnostic checklist you almost want it to be provided as an education tool with photographs and descriptions.... so that people can put these differential diagnoses into their head' (P15, dermatology consultant).</i></p> <p><i>'You would have to develop a criteria that can pick up the beginning, it is in the middle and it</i></p>

		<p><i>is resolving at the end</i> (P18, dermatology trainee).</p> <p><i>'Because there is such a wide differential...how would you exclude all of those and also it can be quite nonspecific sometimes in the early stages'</i> (P12, GP locum).</p> <p><i>'Sometimes the trouble with guidelines, algorithms... you could probably cover 95% but does it mean that actually the atypical 5% then [do not] get diagnosed?'</i> (P20, dermatology consultant).</p>
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## Standards for Reporting Qualitative Research (SRQR)\*

<http://www.equator-network.org/reporting-guidelines/srqr/>

Page/line no(s).

### Title and abstract

<p><b>Title</b> - Concise description of the nature and topic of the study Identifying the study as qualitative or indicating the approach (e.g., ethnography, grounded theory) or data collection methods (e.g., interview, focus group) is recommended</p>	<p>Page 1/line 1-2</p>
<p><b>Abstract</b> - Summary of key elements of the study using the abstract format of the intended publication; typically includes background, purpose, methods, results, and conclusions</p>	<p>Page 2/lines 43-67</p>

### Introduction

<p><b>Problem formulation</b> - Description and significance of the problem/phenomenon studied; review of relevant theory and empirical work; problem statement</p>	<p>Page 4/ lines 91-101</p>
<p><b>Purpose or research question</b> - Purpose of the study and specific objectives or questions</p>	<p>Page 4/lines 100-101</p>

### Methods

<p><b>Qualitative approach and research paradigm</b> - Qualitative approach (e.g., ethnography, grounded theory, case study, phenomenology, narrative research) and guiding theory if appropriate; identifying the research paradigm (e.g., postpositivist, constructivist/ interpretivist) is also recommended; rationale**</p>	<p>Page 7/lines 163-168</p>
<p><b>Researcher characteristics and reflexivity</b> - Researchers' characteristics that may influence the research, including personal attributes, qualifications/experience, relationship with participants, assumptions, and/or presuppositions; potential or actual interaction between researchers' characteristics and the research questions, approach, methods, results, and/or transferability</p>	<p>Page 6/ lines 139-145</p>
<p><b>Context</b> - Setting/site and salient contextual factors; rationale**</p>	<p>Page 6/lines 147-149</p>
<p><b>Sampling strategy</b> - How and why research participants, documents, or events were selected; criteria for deciding when no further sampling was necessary (e.g., sampling saturation); rationale**</p>	<p>Pages 5-6/ lines 122-135</p>
<p><b>Ethical issues pertaining to human subjects</b> - Documentation of approval by an appropriate ethics review board and participant consent, or explanation for lack thereof; other confidentiality and data security issues</p>	<p>Page 5/ lines 112-116</p>
<p><b>Data collection methods</b> - Types of data collected; details of data collection procedures including (as appropriate) start and stop dates of data collection and analysis, iterative process, triangulation of sources/methods, and modification of procedures in response to evolving study findings; rationale**</p>	<p>Page 6-7/ lines 151-158</p>

1 2 3 4 5	<b>Data collection instruments and technologies</b> - Description of instruments (e.g., interview guides, questionnaires) and devices (e.g., audio recorders) used for data collection; if/how the instrument(s) changed over the course of the study	Pages 6-7/ lines 151-158
6 7 8 9	<b>Units of study</b> - Number and relevant characteristics of participants, documents, or events included in the study; level of participation (could be reported in results)	In the results, Page 8/lines 180-181 and Table 1
10 11 12 13	<b>Data processing</b> - Methods for processing data prior to and during analysis, including transcription, data entry, data management and security, verification of data integrity, data coding, and anonymization/de-identification of excerpts	Page 6/ lines 159-161
14 15 16 17	<b>Data analysis</b> - Process by which inferences, themes, etc., were identified and developed, including the researchers involved in data analysis; usually references a specific paradigm or approach; rationale**	Page 7/lines 162-174
18 19 20 21	<b>Techniques to enhance trustworthiness</b> - Techniques to enhance trustworthiness and credibility of data analysis (e.g., member checking, audit trail, triangulation); rationale**	Page 7/ lines 165-174

### Results/findings

22 23 24 25 26 27	<b>Synthesis and interpretation</b> - Main findings (e.g., interpretations, inferences, and themes); might include development of a theory or model, or integration with prior research or theory	Pages 8-17/ lines 179-329
28 29 30	<b>Links to empirical data</b> - Evidence (e.g., quotes, field notes, text excerpts, photographs) to substantiate analytic findings	Pages 8-17/ lines 179-329

### Discussion

31 32 33 34 35 36 37 38	<b>Integration with prior work, implications, transferability, and contribution(s) to the field</b> - Short summary of main findings; explanation of how findings and conclusions connect to, support, elaborate on, or challenge conclusions of earlier scholarship; discussion of scope of application/generalizability; identification of unique contribution(s) to scholarship in a discipline or field	Page 18/lines 348-369, Pages 19-21/391-418
39 40 41	<b>Limitations</b> - Trustworthiness and limitations of findings	Page 19/ lines 370-390

### Other

42 43 44 45 46	<b>Conflicts of interest</b> - Potential sources of influence or perceived influence on study conduct and conclusions; how these were managed	Page 21/line 433-434
47 48 49	<b>Funding</b> – Sources of funding and other support; role of funders in data collection, interpretation, and reporting	Page 1/ lines 22-23

\*The authors created the SRQR by searching the literature to identify guidelines, reporting standards, and critical appraisal criteria for qualitative research; reviewing the reference lists of retrieved sources; and contacting experts to gain feedback. The SRQR aims to improve the transparency of all aspects of qualitative research by providing clear standards for reporting qualitative research.

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\*\*The rationale should briefly discuss the justification for choosing that theory, approach, method, or technique rather than other options available, the assumptions and limitations implicit in those choices, and how those choices influence study conclusions and transferability. As appropriate, the rationale for several items might be discussed together.

**Reference:**

O'Brien BC, Harris IB, Beckman TJ, Reed DA, Cook DA. **Standards for reporting qualitative research: a synthesis of recommendations.** *Academic Medicine*, Vol. 89, No. 9 / Sept 2014  
DOI: 10.1097/ACM.0000000000000388

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# BMJ Open

## An interview study to determine the experiences of cellulitis diagnosis amongst health care professionals in the UK.

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Manuscript ID	bmjopen-2019-034692.R2
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<b>Primary Subject Heading</b>:	Dermatology
Secondary Subject Heading:	Infectious diseases, Qualitative research
Keywords:	DERMATOLOGY, Adult dermatology < DERMATOLOGY, Infectious diseases & infestations < DERMATOLOGY, QUALITATIVE RESEARCH

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1 **Title:** An interview study to determine the experiences of cellulitis diagnosis amongst health  
2 **care professionals in the UK.**

3 **Running head:** Cellulitis diagnosis by health care professionals

4 **Word count:** 3981

5 **Table count:** 4

6 **Figure count:** 1

7 **Supplementary material:** 1

8 **Authors:** M Patel, <sup>1,2</sup> S I Lee, <sup>1</sup> NJ Levell, <sup>3</sup> P Smart, <sup>4</sup> J Kai, <sup>1</sup> KS Thomas, <sup>2</sup> P Leighton, <sup>2</sup>

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20 Nottingham, Nottingham, UK, Email: mpatel59@doctors.org.uk

21  
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24  
25 **Study registration:** Centre of Evidence Based Dermatology website -  
26 [https://www.nottingham.ac.uk/research/groups/cebd/documents/researchdocs/protocol-](https://www.nottingham.ac.uk/research/groups/cebd/documents/researchdocs/protocol-diagnosing-lower-limb-cellulitis-health-care-professionals.pdf)  
27 [diagnosing-lower-limb-cellulitis-health-care-professionals.pdf](https://www.nottingham.ac.uk/research/groups/cebd/documents/researchdocs/protocol-diagnosing-lower-limb-cellulitis-health-care-professionals.pdf)

28  
29 **Data sharing:** No additional data available

## Abstract

**Objectives:** To explore health care professionals (HCPs) experiences and challenges in diagnosing suspected lower limb cellulitis.

**Setting:** UK nationwide.

**Participants:** 20 qualified HCPs, who had a minimum of two years clinical experience as a HCP in the national health service and had managed a clinical case of suspected cellulitis of the lower limb in the UK.

HCPs were recruited from departments of dermatology (including a specialist cellulitis clinic), general practice, tissue viability, lymphoedema services, general surgery, emergency care and acute medicine.

Purposive sampling was employed to ensure that participants included consultant doctors, trainee doctors and nurses across the specialties listed above. Participants were recruited through: national networks,

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3 54 HCPs who contributed to the cellulitis priority setting partnership (PSP), UK Dermatology Clinical Trials  
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6 55 Network, snowball sampling where participants helped recruit other participants, personal networks of the  
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9 56 authors.

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13 57 **Primary and secondary outcomes:** Primary outcome was to describe the key clinical features which inform  
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16 58 the diagnosis of lower limb cellulitis. Secondary outcome was to explore the difficulties in making a  
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19 59 diagnosis of lower limb cellulitis.

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22 60 **Results:** The presentation of lower limb cellulitis changes as the episode runs its course. Therefore,  
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25 61 different specialties see clinical features at varying stages of cellulitis. Clinical experience is essential to  
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28 62 being confident in making a diagnosis, but even amongst experienced HCPs, there were differences in  
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31 63 the clinical rationale of diagnosis. A group of core clinical features were suggested, many of which  
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34 64 overlapped with alternative diagnoses. This emphasises how the diagnosis is challenging, with objective  
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37 65 aids and a greater understanding of the mimics of cellulitis required.

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40 66 **Conclusion:** Cellulitis is a complex diagnosis and has a variable clinical presentation at different stages.  
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43 67 Although cellulitis is a common diagnosis to make, HCPs need to be mindful of alternative diagnoses.

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47 68 **Keywords:** lower limb, cellulitis, diagnosis, health care professionals  
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54 70 **Article summary**

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3 71 Strengths and limitations of this study  
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- 7 72 • The research question was developed from research priorities in the cellulitis priority  
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10 73 setting partnership, involving patients.  
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14 74 • Participants were included nationally around the UK.  
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17 75 • Participants from various specialities that commonly diagnose cellulitis were recruited.  
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20 76 • Our recruitment strategy is most likely to have targeted health care professionals with an  
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23 77 interest in dermatology.  
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26 78 • The size and scope of the sample population is a limitation.  
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25 90 **Introduction**

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29 91 Cellulitis is a frequent presentation in both the community and secondary care, with 60% of  
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32 92 presentations affecting the lower limbs.<sup>1</sup> However, the diagnosis of cellulitis can be challenging,  
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35 93 with up to a third of suspected lower limb cellulitis cases being later diagnosed as other  
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38 94 diagnoses.<sup>2</sup> This results in avoidable hospital admissions and unnecessary antibiotic prescribing  
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41 95 <sup>3</sup> and is further compounded by the lack of validated diagnostic criteria or tools for cellulitis.<sup>4</sup>  
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45 96 A UK cellulitis research priority setting partnership (PSP) determined that improving health care  
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48 97 professionals' (HCPs) diagnostic accuracy is a key priority for future cellulitis research.<sup>5</sup> An  
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51 98 interview study of people with recurrent cellulitis and lymphoedema suggested that patients  
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55 99 often experience difficulties in obtaining a speedy and accurate diagnosis. <sup>6</sup>

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3 100 The aims of this interview study were to explore the HCP experiences and challenges faced in  
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7 101 diagnosing suspected lower limb cellulitis.  
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49 111 **Methods**

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53 112 **Protocol registration and Ethics**  
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For peer review only



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3 113 The final protocol was registered on the Centre of Evidence Based Dermatology (CEBD)  
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6 114 website (9 May 2019). Ethical approval was granted by the Health Research Authority and  
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9 115 Health and Care Research Wales (19/HRA/0485) (30 November 2018). Verbal and written  
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13 116 consent was obtained from each participant.  
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### 17 117 **Patient and public involvement**

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21 118 The research question was developed from research priorities in the cellulitis PSP, involving  
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24 119 patients. A patient representative helped design this study and is a co-author. On publication,  
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27 120 participants will be sent the final manuscript.  
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### 31 121 **Eligibility criteria**

### 35 122 **Selection of participants**

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39 123 Participants were qualified HCPs, who had a minimum of two years clinical experience as a  
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42 124 HCP in the national health service (NHS) and had managed a clinical case of suspected  
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45 125 cellulitis of the lower limb in the UK. Two years' experience was the minimum requirement as  
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48 126 then HCP's will have gained adequate exposure to cellulitis cases. HCPs were recruited from  
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52 127 departments of dermatology (including a specialist cellulitis clinic), general practice, tissue  
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55 128 viability, lymphoedema services, general surgery, emergency care and acute medicine.  
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3 129 Purposive sampling was employed to ensure that participants included consultant doctors,  
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6 130 trainee doctors and nurses across the specialties listed above. Participants were recruited  
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- 13 132 • National networks
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16 133 • HCPs who contributed to the cellulitis PSP
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19 134 • UK Dermatology Clinical Trials Network
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22 135 • Snowball sampling where participants helped recruit other participants
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26 136 • Personal networks of the authors
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29 137 Potential participants were approached and recruited by email. Data collection and analysis  
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32 138 were undertaken concurrently and sampling ceased when thematic saturation had been  
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35 139 achieved (i.e. new interviews generated no new insights).<sup>7</sup>

#### 38 140 **Researcher characteristics**

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42 141 Interviews were conducted by MP (male), and coded and analysed by MP and SIL (female)  
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45 142 (both general practitioner (GP) trainees who had managed clinical cases of cellulitis previously).  
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48 143 Both MP and SIL attended qualitative methodology training courses. The broader research  
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51 144 group included experienced clinical-academics (JK (academic GP) and NL (clinical professor of  
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3 145 dermatology), a patient representative (PS) and senior qualitative experts (JK and PL). Three  
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6 146 participants had clinical interactions with the interviewer in the past, but not regarding cellulitis.  
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### 10 147 **Interview setting**

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14 148 Each participant took part in a single, semi-structured, qualitative interview. Two interviews were  
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17 149 face to face, with the remaining via telephone. Written consent was gained from participants,  
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21 150 with additional verbal consent gained before the interview. All participants received a £20  
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24 151 reimbursement voucher or donated this fee to the British Skin Foundation charity.  
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### 27 152 **Data collection**

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31 153 Prior to the interview, participants were asked to reflect upon their most recent experiences of  
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34 154 making a cellulitis diagnosis, focusing on the typical presentations, challenging cases and  
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37 155 differential diagnoses.  
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42 156 A topic guide, informed by a prior systematic review and interview study,<sup>8</sup> was used to structure  
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45 157 the interview (Supplementary material). However, participants were urged to propose and/or  
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48 158 expand on topics which they felt were relevant to their experience of diagnosis. New topics were  
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51 159 then added to the topic guide for subsequent interviews.  
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### 55 160 **Data processing**

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3 161 Interviews were audio-recorded and transcribed. Transcripts were checked (by MP) and data  
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6 162 managed using QSR NVivo 12 software.  
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### 10 11 163 **Data analysis** 12

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14 164 Analysis was inductive, searching for themes in the data. A structured, systematic, multi-stage  
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17 165 approach to thematic analysis was followed.<sup>9</sup> Coders immersed themselves in the data, by  
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21 166 reading the data set before coding. Data were coded manually by MP, with SIL also  
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24 167 independently coding a third of the transcripts. A list of each code, with a brief description was  
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27 168 then used to group the codes into theme-piles. Themes were defined and refined, with sub-  
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31 169 themes also developed.  
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34 170 Uncertainties in coding and thematic organisation were resolved in discussion with the other  
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37 171 authors. Data collection and analysis was concurrent. The final codebook was agreed by all  
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41 172 authors and is presented in Figure 1. The interviewer kept a reflexive research diary, logging  
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44 173 intuitive thoughts and immediate reflections after each interview. These reflections, as well as  
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47 174 queries around data collection, handling and interpretation were then discussed at regular  
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51 175 research meetings.  
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## 180 Results

181 Twenty HCPs were interviewed (Table 1). Interviews were conducted between 19 March and 11  
 22 June 2019, with a mean duration of 29 minutes.

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**Table 1: Characteristics of the participants**

Participant	Ethnicity	Clinical role	Number of times they have diagnosed cellulitis	Time since they last diagnosed cellulitis
1	Asian British	GP	>50	One week ago
2	White British	Acute medicine/infectious disease consultant	>50	One week ago
3	White Irish	GP	>50	Three weeks ago
4	White British	Acute medicine consultant	>50	Last four weeks
5	White British	Acute medicine consultant	>50	One week ago

6	White British	Tissue viability nurse	10-50	Less than one week
7	White British	Lymphoedema specialist nurse	>50	One week ago
8	Asian British	Emergency medicine consultant	>50	Less than one week
9	Asian British	Dermatology consultant	10-50	Four weeks ago
10	White British	District nurse	>50	Last three months
11	Black	GP trainee	10-50	Less than one week
12	White British	GP locum	10-50	Two weeks ago
13	White British	GP out of hours	>50	Two weeks ago
14	White British	Dermatology specialist nurse	>50	Last three months
15	White British	Dermatology consultant	10-50	Last 12 months
16	Mixed	Surgical trainee	10-50	Last four weeks
17	White British	Community advanced nurse practitioner	>50	Less than one week
18	White British	Dermatology trainee	>50	Four weeks ago
19	White British	Emergency medicine consultant	>50	Last three months
20	White British	Dermatology consultant	>50	Less than one week

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4 185 **Main findings**

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8 186 Four key themes were identified: 1) The patient presentation; 2) Challenges leading to  
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11 187 diagnostic uncertainty; 3) Strategies to improve diagnosis; 4) The need for an objective  
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14 188 diagnostic aid, with further classification into sub-themes. How the codes mapped onto the  
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17 189 overarching themes are shown in Table 2.  
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49 199 **Table 2: How the codes mapped onto themes**  
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Themes	Sub-themes	Codes
<b>The patient presentation</b>	The typical patient and risk factors	<ul style="list-style-type: none"> <li>• Typical cellulitis presentations</li> </ul>
		<ul style="list-style-type: none"> <li>• Factors that increase the likelihood of cellulitis diagnosis</li> </ul>
	Confidence in diagnosis	<ul style="list-style-type: none"> <li>• Most suitable HCP to diagnose cellulitis</li> <li>•</li> </ul>
		<ul style="list-style-type: none"> <li>• Experience guides diagnosis</li> </ul>
	Cases of misdiagnoses	<ul style="list-style-type: none"> <li>• Missed/delayed diagnosis of cellulitis (final diagnosis)</li> </ul>
		<ul style="list-style-type: none"> <li>• Missed/delayed diagnosis of cellulitis (initial diagnosis)</li> </ul>
Differential diagnoses	<ul style="list-style-type: none"> <li>• List of alternative diagnosis</li> </ul>	
<b>Challenges leading to diagnostic uncertainty</b>	Continuum of clinical features	<ul style="list-style-type: none"> <li>• Changes in clinical presentation</li> </ul>
	A subjective diagnosis	<ul style="list-style-type: none"> <li>• Reasons why cellulitis diagnosis is challenging</li> </ul>
	Community challenges	<ul style="list-style-type: none"> <li>• Seeing patients part way through assessment and management</li> </ul>
		<ul style="list-style-type: none"> <li>• Follow up of patients</li> </ul>
	The role of 'defensive' medicine	<ul style="list-style-type: none"> <li>• Sepsis as a concern</li> <li>• Medico legal issues as a factor</li> </ul>
		<ul style="list-style-type: none"> <li>• Fear of missing more serious differentials</li> </ul>
Patient specific factors	<ul style="list-style-type: none"> <li>• Other factors influencing diagnosis</li> </ul>	
<b>Strategies to improve diagnosis</b>	Using time as a guide	<ul style="list-style-type: none"> <li>• Time and safety netting approach</li> <li>•</li> </ul>
	Trial of treatment	<ul style="list-style-type: none"> <li>• Trial of treatment guides diagnosis</li> </ul>



		•
	Biochemical investigations	• Investigations to aid diagnosis
	Seeking advice	• Discussing diagnosis with colleagues
	Further education	• Suggestions on what may improve diagnosis
<b>The need for an objective diagnostic aid</b>	A diagnostic algorithm	• Views on diagnostic aids for HCP
	Indices for an algorithm	• Clinical features to include in diagnostic algorithm

## 200 **Diagnosis of cellulitis**

### 201 *The typical patient and risk factors*

202 In general practice, the typical patient described by participants included older adults with co-  
 203 morbidities; concerns of possible cellulitis cases were often raised by district nursing colleagues.

204 Emergency care and acute services described people who presented with features of systemic  
 205 compromise. Both infectious disease and general surgery services often managed intravenous  
 206 drug users who were at risk of deeper infection.

207 Factors that HCPs stated increased the likelihood of cellulitis were: features of systemic upset  
 208 including fever, malaise, rigors; co-existing injury or infection such as tinea, superficial  
 209 ulceration, previous history of cellulitis, previous history of dermatological conditions such as

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3 210 eczema, diabetes, immunosuppressive medications and those with no fixed abode with social  
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7 211 and health risks. Bilateral symptoms were commonly described by participants as a factor  
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10 212 increasing the likelihood of chronic, systemic pathologies rather than cellulitis.  
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### 13 213 *Confidence in diagnosis*

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18 214 One dermatologist explained how being more aware of the differential diagnoses made them  
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21 215 more likely to accurately diagnose cellulitis, especially compared to junior colleagues. Generally,  
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24 216 HCPs with more clinical experience felt more confident with diagnosis, as they appreciated the  
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27 217 presentation with more observed cases '*I would say it is just experience [helping diagnosis], a*  
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30 218 *lot of the juniors that come into A&E have not seen that many cellulitis [cases]* (P19, emergency  
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34 219 care consultant, 10 years clinical experience).  
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38 220 A dermatology trainee felt seeing less cellulitis cases during their training compared to their  
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41 221 senior colleagues historically, and therefore not getting as much exposure, hindered accurate  
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### 48 49 50 224 *Cases of misdiagnoses*

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3 225 Trauma related skin changes was frequently an initial misdiagnosis in the emergency  
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7 226 department. When discussing cases of uncertainty, where cellulitis was the initial suspected  
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10 227 diagnosis, one GP described a case of venous eczema which was managed with repeated  
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13 228 antibiotics '*Generally anything that is red and hot on the legs is treated with antibiotics*' (P1, GP,  
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16 229 >13 years clinical experience). Chronic rashes were frequently seen by dermatology and  
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19 230 infectious disease discussed lymphoma cases initially referred as cellulitis '*We did see [patients]*  
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22 231 *coming in with "Oh this must be a resistant cellulitis", have got a swollen limb that might be a*  
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25 232 *little bit red and it turns out to be some horrible form of lymphoma*' (P2, infectious disease  
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29 233 consultant, 25 years clinical experience).  
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33 234 The importance of a correct diagnosis is key, as two participants discussed the possibility of  
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36 235 prophylactic antibiotics for patients with recurrent cellulitis. A dermatology consultant explained  
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39 236 how misdiagnosis can result in inappropriate and costly admissions to the ward.  
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### 43 237 *Differential diagnoses*

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47 238 A frequent diagnosis of uncertainty for primary and emergency care was deep vein thrombosis  
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50 239 (DVT), as the clinical features of cellulitis can overlap '*One thing that is always a problem is leg*  
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53 240 *swelling...it is difficult to ascertain between DVT and cellulitis*' (P8, emergency care consultant,  
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20 years clinical experience). Common differential diagnoses discussed by participants, which they observed in their clinical practice, with discriminating features from cellulitis that they described, are shown in Table 3.

**Table 3:** Differential diagnoses of lower limb cellulitis discussed by participants

Differential diagnoses	Key differentiating factors from cellulitis
Chronic heart failure causing oedema	Chronic, bilateral, lack of mobility, breathless, cardiac history (P1,GP;P14,dermatology specialist nurse)
Venous eczema	Usually chronic with hemosiderin scaling, itching, crusting, likely bilateral, possibly eczema elsewhere on body, less well defined, (P3,GP;P15, dermatology consultant)
Thrombophlebitis	Tender, localised, hard, lumpy rash around an often-thickened vein (P3,GP;P5,acute medicine consultant;P12,GP locum)
Erythema nodosum	Multiple, discrete swellings (P13,GP out of hours)
Deep vein thrombosis	Pain is usually deep in calf rather than superficial, less sharply demarcated and less intense erythema, diffuse swelling of limb, can be young, can be intravenous drug users, high DVT wells score, fewer systemic features (P2,infectious disease consultant;P12,GP locum;P13,GP out of hours)

Lymphoedema	Chronic, bilateral, usually less painful, thickened warty skin in the long-term, normal inflammatory markers (P9,dermatology consultant;P18,dermatology trainee)
Allergic reaction to insect bites	Central puncture mark, itch, when acute, developing lichenified erythema when chronic (P2,infectious disease consultant)
Lipodermatosclerosis	Often bilateral, systemically well, tight non tender skin with inverted champagne bottle appearance (P4,acute medicine consultant; P20,dermatology consultant)
Necrotising fasciitis	Crepitus, rapidly spreading, septic, very tender (P5,acute medicine consultant; P16, surgical trainee)
Wound infection	Local to the wound, covers small area, yellow exudate, strong odour (P10,district nurse; P16,surgical trainee)
Baker's cyst	Unilateral popliteal swelling, suddenly more tender on rupture (P15,dermatology consultant)

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## 247 Challenges leading to diagnostic uncertainty

### 248 *The continuum of clinical features*

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3 249 Participants described how the presentation of lower limb cellulitis changed as the episode ran  
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7 250 its course. This was influenced by when patients seek clinical review and meant that different  
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10 251 specialties observed clinical features at varying stages of cellulitis.

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14 252 In dermatology services, presentations were seen later in the episode. However, partial  
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17 253 treatment and response did make the diagnosis challenging as the initial typical features of  
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20 254 cellulitis may then vary. However, seeing patients later in the journey allowed dermatologists to  
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23 255 appreciate the progression of clinical features '*I learnt to appreciate much more that [cellulitis] is*  
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25  
26 256 *coming up, it is happening and that it is fading away... When I was [junior], I was seeing*  
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30 257 *[cellulitis] at the beginning and middle stages, trying to diagnose it, but in dermatology you're*  
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33 258 *seeing it more at that other end of the spectrum...so I think there is a lot [to be] learnt about*  
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36 259 *seeing that pattern developing and progressing and then resolving'* (P18, dermatology trainee,  
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39 260 eight years clinical experience)

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43 261 Importantly for dermatologists, other more serious pathologies such as a DVT had often been  
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46 262 ruled out.

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50 263 *A subjective diagnosis*  
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3 264 One GP explained how there is no specific test that can aid diagnosis, thus subjective  
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6 265 assessment can lead to different diagnoses *'I think the fact that there is no specific diagnostic*  
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10 266 *test... and two different people can look at [possible cellulitis] and come up with two different*  
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13 267 *answers'* (P1, GP, >13 years clinical experience). She added how this is further influenced by  
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16 268 previous experiences, including how long and where HCPs have trained  
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### 26 271 *Community challenges*

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30 272 In the community, additional challenges for GPs were not being familiar with the patient's  
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33 273 background history, seeing a patient for the first time, or taking over care part way through the  
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36 274 patient journey. Working as a locum doctor with a lack of follow up available, often led to  
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39 275 treatment when unsure of the diagnosis *'You've not met the patient before and sometimes*  
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42 276 *you're not going to be able to follow them up so you probably are more likely to give antibiotics'*  
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46 277 (P12, GP locum, seven years clinical experience). Limited resources to see patients, such as  
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49 278 not being able to conduct an urgent home visit, also influenced diagnosis and subsequent  
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52 279 management by GPs.  
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280 *The role of 'defensive' medicine*

281 HCPs in the community, emergency care and surgery were particularly wary of missing a more  
282 serious diagnosis, which needed to be ruled out first, such as DVT and necrotising fasciitis (NF)  
283 *'I think you would want to rule out DVT first because if you miss that then that is... a problem'*  
284 (P1, GP, >13 years clinical experience; P16, female, surgical trainee, five years clinical  
285 experience). Many HCPs also mentioned '*sepsis*' when discussing clinical features and  
286 diagnosis. This may be leading to an over diagnosis of cellulitis due to concerns of medico legal  
287 complaints of missing an infection which could then get worse *'We're all risk adverse aren't we?*  
288 *We would rather make sure we weren't sued because we had missed someone with an*  
289 *infection'* (P2, infectious disease consultant, 25 years clinical experience).

290 *Patient specific factors*

291 Participants found people with pigmented skin, lymphoedema and with nonspecific symptoms  
292 particularly difficult to diagnose in the acute setting *'One of these classical patients that comes*  
293 *in hasn't got a rash ... [or] the features of swelling, redness, rash and pain in the leg but they*  
294 *come in none specifically unwell ... I think those patients are much trickier [to diagnose cellulitis]'*  
295 (P5, acute medicine consultant, 16 years clinical experience). One nurse described another



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3 296 diagnostic challenge was when a patient presents with chronic skin changes or a recent episode  
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7 297 of cellulitis with continuing signs '*People with chronic red [legs], their legs are red most of the*  
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10 298 *time... the skin takes so long to settle, so they could have had cellulitis four weeks ago and it is*  
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13 299 *still red*' (P17, advanced nurse practitioner, 20 years clinical experience).

### 300 **Strategies used to reduce uncertainty**

#### 301 *Using time as a guide*

302 In cases where the HCP was not sure of the diagnosis, different strategies were employed.  
303 Using time to allow further clinical features to develop, with appropriate safety netting was a  
304 commonly used approach. This was easier when follow-up appointments were available in the  
305 community, but was also done in the acute setting '*So if they were well... then I would bring*  
306 *them back to clinic the next day or two*' (P4, acute medicine consultant, 17 years clinical  
307 experience). But follow-up in secondary care was difficult, often not done and can be a missed  
308 opportunity to learn from incorrect diagnoses previously.

#### 309 *Trial of treatment*

310 Some HCPs started antibiotics for a suspected cellulitis and reviewed the response to help  
311 provide the diagnosis retrospectively '*Cellulitis...was the easiest thing to try and treat so I think*  
312 *that definitely pushed [me] to try some antibiotics and see if this is an infection*' (P11, GP)

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3 313 trainee, six years clinical experience). A major concern highlighted by one GP with this  
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7 314 approach was antibiotic resistance and side effects. However, overall, there was a common  
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10 315 understanding in primary care why this approach was taken in some instances.  
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### 13 316 *Biochemical investigations*

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17 317 In primary care, one doctor described how blood tests and cultures were rarely done to  
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20 318 diagnose cellulitis, as such patients would need to be seen in secondary care. Blood cultures  
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23 319 were requested by the infectious disease physician if it was an atypical infection, but a  
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27 320 challenge described by one dermatology consultant was that organisms are not isolated in the  
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30 321 majority of patients. Swabs were done for discharging wound infections, mainly by district  
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33 322 nurses or prior to discussion with microbiology, when see by dermatologists.  
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37 323 An emergency physician and surgical trainee explained how blood tests and imaging such as x-  
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39  
40 324 rays are important to check for osteomyelitis. The blood tests commonly requested by  
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43 325 secondary care HCPs were white cell count (WCC) and C-reactive protein (CRP) for infection  
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46 326 with one dermatologist stating how changes in blood test results were important when taking  
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49 327 referrals for suspected cellulitis '*[With cellulitis]...you expect a) it is unilateral, b) you want some*  
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51  
52 328 *inflammatory markers which are raised, at least a reasonable WCC and CRP and if it is normal*  
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329 *it is not going to be cellulitis'* (P9, dermatology consultant, 10 years clinical experience).

330 However, one challenge with interpreting blood tests was in the group partially treated with  
331 antibiotics, who have improving blood tests but limited clinical response. A biomarker or point of  
332 care test for cellulitis were suggested as investigations to aid diagnosis by one dermatology  
333 consultant and one GP respectively.

#### 334 *Seeking advice*

335 Another approach during uncertainty was to discuss with colleagues. In the community the  
336 nurse may ask the GP to review and vice versa. In hospital, specialists in infectious disease,  
337 dermatology, microbiology and general/plastic surgeons are most often contacted for review.

#### 338 *Further education*

339 Many HCPs mentioned teaching sessions to improve diagnosis, both at the undergraduate and  
340 postgraduate level. One GP stated that real life clinical cases were felt to be important for  
341 teaching, rather than focusing on pictures '*It is all very well seeing pictures but pictures aren't*  
342 *that helpful sometimes, it is how it feels sometimes that makes a difference and actually seeing*  
343 *it in the flesh is very different to seeing even good quality pictures, so I do think that clinical*  
344 *exposure [is important]* (P13, GP, 20 years clinical experience).

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4 345 A dermatology consultant suggested that a key area of education amongst HCPs was being  
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7 346 aware of differential diagnoses for frontline services '*It is not something people will have put a*  
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10 347 *lot of thought into, the differentials, and I think the focus needs to be on teaching the frontline*  
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13 348 *staff* (P15, dermatology consultant, 18 years clinical experience).

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17 349 One trainee who worked in a specialist cellulitis clinic found that seeing many cases helped  
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20 350 improve her recognition of cellulitis.

## 21 22 23 24 351 **The need for an objective diagnostic aid**

### 25 26 27 352 *A diagnostic algorithm*

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31 353 Many participants mentioned developing a diagnostic algorithm, similar to the Wells score for  
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34 354 DVT. A GP explained how this may also help GPs make a validated clinical decision when  
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37 355 colleagues such as district nurses are suspecting cellulitis and the patient cannot be seen  
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40 356 quickly. A dermatology nurse described how she often used checklists and how an algorithm  
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43 357 would help HCP's not to miss any clinical features '*[A checklist] could help people that weren't*  
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46 358 *experienced or confident enough...it just gives you something to think about like "oh I hadn't*  
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49 359 *thought about the heat"*' (P14, dermatology nurse, nine years clinical experience).

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3 360 One dermatology consultant suggested that a diagnostic checklist should be more of an  
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6 361 educational tool to help rule out other differential diagnoses '*For a diagnostic checklist you*  
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9 362 *almost want it to be provided as an education tool with photographs and descriptions... so that*  
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12 363 *people can put these differential diagnoses into their head* (P15, dermatology consultant, 18  
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16 364 years clinical experience).

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20 365 A dermatology trainee felt that the indices of a checklist would have to reflect how cellulitis  
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23 366 changes through the course of the episode. Other challenges described by participants,  
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26 367 regarding developing an algorithm were the number of alternative diagnoses, with features that  
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29 368 often overlapped with cellulitis and vague initial features. Another concern highlighted by a  
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32 369 dermatology consultant was that algorithms will miss patients who may present with atypical  
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35 370 features '*Sometimes the trouble with guidelines, algorithms... you could probably cover 95% but*  
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38 371 *does it mean that actually the atypical 5% then [do not] get diagnosed?* (P20, dermatology  
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42 372 consultant, 42 years clinical experience).

### 43 44 45 46 373 *Indices for an algorithm*

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50 374 The key clinical features HCPs suggested to include in a diagnostic algorithm for lower limb  
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53 375 cellulitis were: unilateral, pain, erythema, warmth of limb, pyrexia, swelling, acute onset, trauma

376 to the limb, break in the skin, single area affected, clear demarcation, exudate, flu like malaise,  
 377 tracking rash, shiny, tenses skin, previous cellulitis, co-existing immunosuppression, co-existing  
 378 skin conditions, clinical observations for sepsis, negative Wells score and patient concern. No  
 379 HCP suggested blood tests were a priority in the algorithm, but a GP trainee suggested it could  
 380 be included in a modified algorithm in secondary care, similar to the CURB-65 score used for  
 381 pneumonia.

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383 Additional quotes from participants are shown in Table 4.

384 **Table 4:** Additional quotes from participants, grouped into themes and subthemes

Themes	Subthemes	Participant quotes
The patient presentation	Confidence in diagnosis	<i>'I probably thought more presentations were [cellulitis] as a junior doctor... I probably didn't really recognise that sort of stretched skin appearance.. I think that has come along as part of just experience over the years, so I probably diagnosed more cellulitis inappropriately as a more junior doctor'</i> (P13, GP out of hours, 20 years clinical experience)
	Cases of misdiagnoses	<i>'One of the nurse practitioners had seen ankle swelling and the patient thought it... he played some cricket two or three days ago and after one or two days the swelling appeared and she thought that it was just a sprain but next day he represented, I saw him and it looked more like cellulitis because it was quite red, localised area... on close examination I could see a couple of scratches around the ankle so that was maybe the source of cellulitis spreading on the leg'</i> (P8, emergency care consultant, 20 years clinical experience)

		<i>'There are too many chronic rashes that get referred [to dermatology] as cellulitis'</i> (P18, dermatology trainee, eight years clinical experience)
<b>Challenges leading to diagnostic uncertainty</b>	<b>Continuum of clinical features</b>	<i>'Usually the patient is already admitted ... [the referring team] have tried [multiple antibiotics], but nothing is happening, "please can you come and tell us what is going on?"'</i> (P9, dermatology consultant, 10 years clinical experience)  <i>'There are varying ranges of erythema, from a little bit of light pinkness to rip roaring hot red, tender, well demarcated, unilateral; the classic sort of textbook stuff'</i> (P18, dermatology trainee, eight years clinical experience)  <i>'Virtually every patient that I see...they have had their d-dimer and their duplex done so [DVT] is usually a diagnosis that has been excluded'</i> (P20, dermatology consultant, 42 years clinical experience)
	<b>Community challenges</b>	<i>'If you know the patient and you know that they have recurrent cellulitis, someone had seen it like a district nurse and it is Friday afternoon and you can't get out [for a visit].. you would make a judgement call'</i> (P1, GP, >13 years clinical experience)
	<b>The role of 'defensive' medicine</b>	<i>'We're so much more aware of things like sepsis... looking at any kind of signs of infection'</i> (P10, district nurse, 25 years clinical experience)
<b>Strategies to improve diagnosis</b>	<b>Using time as a guide</b>	<i>'All you can really do is reassure the patient and say...I don't see any clear evidence of cellulitis but we will keep an eye on it.. you give safety net advice to the patients'</i> (P18, dermatology trainee, eight years clinical experience)
	<b>Trial of treatment</b>	<i>'[My concerns with this approach] are antibiotic resistance and side effects...especially in older groups...I would say probably that is not the best approach'</i> (P3, GP, 18 years clinical experience)
	<b>Biochemical investigations</b>	<i>'If I am thinking about doing blood tests...it is unlikely that I am going to continue managing them in the community'</i> (P11, GP trainee, six years clinical experience)

		<i>'I would never not diagnose somebody [with cellulitis] just because their inflammatory markers are normal' (P5, acute medicine consultant, 16 years clinical experience)</i>
	<b>Further education</b>	<p><i>'You very quickly just get entrenched in...your preferences for diagnoses and it is often good to refresh' (P11, GP trainee, six years clinical experience)</i></p> <p><i>'I only did two weeks [of dermatology] as a medical student... but certainly increasing dermatology teaching at an earlier stage would make a massive difference' (P13, GP, 20 years clinical experience).</i></p> <p><i>'Pattern recognition and [seeing] variation in the progression of the rash [are important], thereby appreciating the 'life of rashes' (P18, dermatology trainee, eight years clinical experience).</i></p>
<b>The need for an objective diagnostic aid</b>	<b>A diagnostic algorithm</b>	<p><i>'I think it can be helpful to have those objective measures [of an algorithm], if it was accepted and validated as a reasonable measure of cellulitis, I think I would actually use that' (P11, GP trainee, six years clinical experience).</i></p> <p><i>'You would have to develop a criteria that can pick up the beginning, it is in the middle and it is resolving at the end' (P18, dermatology trainee, eight years clinical experience).</i></p> <p><i>'Because there is such a wide differential...how would you exclude all of those and also it can be quite nonspecific sometimes in the early stages' (P12, GP locum, 7 years clinical experience).</i></p>

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For peer review only

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## 407 Discussion

### 408 Summary

409 This study found that the presentation of lower limb cellulitis changes as the episode  
410 progresses, leading to variation in the clinical features, seen in different clinical settings. This  
411 may be reflected in the range of typical differential diagnoses that specialities discussed and  
412 has been described in literature.<sup>10</sup>

413 Clinical experience was described as an important factor in making a more accurate diagnosis.  
414 Dermatologists have previously been suggested as the ideal HCP to diagnose cellulitis.<sup>11</sup>  
415 However, the clinical reasoning behind a diagnosis were contradictory between some HCPs.

416 A core group of clinical features to diagnose cellulitis were suggested. But the challenge is that  
417 these features can overlap with other pathologies, irrespective of how likely these are.<sup>12</sup> More  
418 serious pathologies then need to be ruled out first, both for the safety of the patient and to avoid  
419 medico-legal consequences.

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3 420 Suggestions to improve the accuracy of diagnoses included developing a diagnostic algorithm  
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7 421 which could objectively help HCPs with different levels of experience.<sup>13</sup> The challenge with a  
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10 422 diagnostic algorithm is that it would need to incorporate the various stages of a cellulitis episode  
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13 423 and therefore various versions of an algorithm might be required.  
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17 424 Importantly, having a greater understanding of the alternative diagnoses is required, especially  
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20 425 when the features are vague, atypical or not responding to antibiotic treatment. Educating both  
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23 426 doctors and nurses, using real life clinical scenarios and a focus on differential diagnoses, was  
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26 427 also discussed and may be an initial feasible approach to improve diagnostic accuracy. A  
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29 428 visually based computerized diagnostic decision support system, focusing on differential  
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32 429 diagnoses, has been shown to improve the diagnostic accuracy of cellulitis.<sup>14</sup>  
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### 37 430 **Strengths and limitations**

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40 431 A key strength of this study that participants were included nationally around the UK, across  
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43 432 various specialities that commonly diagnose cellulitis, with both nurses and doctors of varying  
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46 433 clinical experience.

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50 434 Like similar studies, the size and scope of the sample population is a limitation of this work.  
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53 435 Whilst we argue that our findings are transferable to other settings, we acknowledge that those  
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3 436 interviewed were perhaps more interested and better informed about dermatology than many  
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7 437 HCPs. This was a function of our purposive sampling, and the likelihood that those interested in  
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10 438 cellulitis were more likely to consent to an interview. Furthermore, the participants in this study  
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13 439 were mainly female doctors. This may not be representative of the workforce in non-UK  
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16 440 countries; therefore the transferability of our findings may be limited.

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20 441 Some participants were unable to fully describe their clinical rationale behind diagnostic  
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23 442 decisions during the interview. This may be because they have developed an intuitive, pattern-  
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26 443 recognition, approach in decision-making with experience. Such heuristic diagnostic processes  
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30 444 in dermatology are well documented.<sup>15</sup>

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34 445 As the interviewer was a fellow clinician, interviewees may not have fully shared the details of  
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37 446 cases that were misdiagnosed or where diagnoses were delayed due to social desirability bias  
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40 447 or fear of litigation. Clinical researcher bias was unavoidable, as the interviewer had clinical  
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43 448 insight into cellulitis. However, non-clinicians within the broader authorship group were also  
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46 449 involved with coding and analysis of the interviews.

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50 450 Three participants were known to the interviewer, which can lead to response bias, however the  
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53 451 interviewer felt this also allowed an honest, open discussion.

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11 454 **Comparison with existing literature**

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15 455 To our knowledge, this is the first interview study undertaken with health care professionals,  
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18 456 discussing their experiences of cellulitis diagnosis. Our findings on the clinical features of  
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21 457 cellulitis, differential diagnoses and also the need to be aware of mimics have been described in  
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24 458 previous review articles.<sup>10</sup> A previous review also described cases of misdiagnosis and  
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27 459 emerging approaches to improve diagnoses,<sup>8,16</sup> which were echoed in this study. The  
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30 460 diagnostic challenges of infection in primary care, due to atypical presentations and lack of  
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33 461 diagnostic tests has previously been described.<sup>17</sup> Using treatments such as antibiotics as  
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36 462 diagnostic aids and discussing with colleagues when uncertain about a diagnosis are common  
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39 463 strategies.<sup>18,19</sup> Litigation and fear missing a diagnosis has also been well documented in  
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42 464 literature.<sup>20</sup>

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48 465 **Implications for research and practice**

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52 466 This study has highlighted that HCPs need to be aware that cellulitis can present with different  
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55 467 features at various stages of the acute episode and need to consider the cellulitis mimics. With

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3 468 a current shift in health care resulting in trained nurses now managing more acute  
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7 469 presentations,<sup>21</sup> upskilling nurses in cellulitis could be part of the solution.  
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10 470 Many HCPs felt confident in making an accurate diagnosis, often guided by experience and  
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13 471 intuition, but found it difficult to verbalise the key distinguishing features. This makes it difficult  
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17 472 for the clinical experience to be shared amongst other colleagues, especially less experienced  
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20 473 or junior HCPs. Acquiring this insight is important to improve diagnostic accuracy, which can  
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23 474 prevent avoidable antibiotic prescribing and hospital admissions. To overcome this, further  
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26 475 qualitative research is required to identify the clinical reasoning behind the expert process of  
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29 476 making a diagnosis, perhaps using clinical cases and pictures. This will form the basis of the  
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32 477 proposed solution of focused education and clinical features to be included in a diagnostic aid.  
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36 478 The challenge with further education for HCPs is that information needs to be accessible for  
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39 479 everyone, whilst information overload can lead to a reduction in the quality of decisions.<sup>22</sup>  
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43 480 Some indices and risk factors for a diagnostic algorithm have been identified in this study and  
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46 481 previous studies,<sup>23</sup> as well as key distinguishing features from differential diagnosis, but these  
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49 482 need validating with larger studies and an expert consensus setting exercise.  
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## 53 483 **Conclusion**

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3 484 This interview study has shown that cellulitis is a complex diagnosis. Not only does the core  
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7 485 features overlap with other diagnoses, the presentation of cellulitis changes as the episode  
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10 486 progresses. Although cellulitis is a common diagnosis to make, and whilst further research in  
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13 487 developing diagnostic aids needs to be undertaken, simply being aware of the cellulitis mimics  
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16 488 may help improve diagnostic accuracy.  
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## 41 495 **Competing interest**

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45 496 None declared  
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## 49 497 **Author contributions**

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53 498 **M Patel** was involved with the design of the study, collection and analysis of data, drafting the  
54  
55 499 manuscript and final approval of the manuscript.  
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4 500 **S I Lee** was involved with the design of the study, analysis of data, drafting the manuscript and  
5 501 final approval of the manuscript.  
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7 502 **NJ Levell** was involved with the design of the study, analysis of data, drafting the manuscript  
8 and final approval of the manuscript.  
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11 504 **P Smart** was involved with the design of the study, analysis of data, drafting the manuscript and  
12 505 final approval of the manuscript.  
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15 506 **J Kai** was involved with the design of the study, analysis of data, drafting the manuscript and  
16 507 final approval of the manuscript.  
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19 508 **KS Thomas** was involved with the design of the study, analysis of data, drafting the manuscript  
20 and final approval of the manuscript.  
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23 510 **P Leighton** was involved with the design of the study, analysis of data, drafting the manuscript  
24 and final approval of the manuscript.  
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**Figure 1: Standardised codebook used by two independent coders**

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595 **Supplementary Material**

596 **Topic guide used to structure the interview**

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## Codes used

- Trial of treatment guides diagnosis
- Discussing diagnosis with colleagues
- Time and safety netting approach
- Patients who self-diagnose and treat
- Approach when HCPs do not agree with patient self-diagnosis
- Patients involved with diagnosis with the HCP
- Typical cellulitis presentations
- Clinical features of cellulitis
- Factors that decrease the likelihood of cellulitis diagnosis
- Factors that increase the likelihood of cellulitis diagnosis
- Investigations to aid diagnosis
- Missed/delayed diagnosis of cellulitis (final diagnosis)
- Missed/delayed diagnosis of cellulitis (initial diagnosis)
- Patient finds it difficult to accept it is not cellulitis
- Reasons why cellulitis diagnosis is challenging
- Suggestions on what may improve diagnosis
- Views on diagnostic aids for HCP
- Views on diagnostic aids for patients
- Views on how well HCP make diagnosis
- Experience guides diagnosis
- Seeing patients part way through assessment and management
- Differential diagnoses
- Sepsis as a concern
- Medico legal issues as a factor
- Follow up of patients
- Most suitable HCP to diagnose cellulitis
- Fear of missing more serious differentials
- Clinical features to include in diagnostic algorithm
- Other factors influencing diagnosis

1 **If the participant has a recent case of cellulitis that they can discuss:**

2 **Can you tell me about a case of cellulitis that you diagnosed?**

3 Prompts:

- 4 • What thoughts go through your head when you are considering a diagnosis of cellulitis?
- 5 • What symptoms do you ask about? Local? General?
- 6 ▪ What signs do you look for? Local? General?
- 7 ▪ Are there any specific signs/symptoms you rely on to help?
- 8 ▪ Did you do any tests?
- 9 ▪ Did you seek advice from anyone else?
- 10 ▪ Were you concerned that this may not be cellulitis?
- 11 ▪ If you were concerned, why?
- 12 ▪ Was there anything challenging about this case?
- 13 ▪ How did you address these challenges?
- 14 ▪ How confident were you that this was cellulitis on a 1-10 scale when you first saw the patient?
- 15 ▪ Did the patient discuss any self-diagnoses?
- 16 ▪ Did any external factors such as time influence your decision?
- 17 ▪ Did the patient come back to see you again?
- 18 ▪ Would you change your approach if the same case presented again?
- 19 ▪ Is this a typical case you see?
- 20 ▪ What are the main differential diagnoses you see?

24 Repeat the above for a maximum two cases that the participants may have for the interview (repeat twice  
25 only if the participant has no delayed/incorrect cases below).

27 **If the participant has a case where the diagnosis was delayed or incorrect (can be initially either  
28 seen by same health care professional or a colleague, but preferably the same person)**

29 Prompts:

- 30 • Did you see the patient on initial presentation or was it a colleague?
- 31 • If it was another colleague, what specialty did they work in?
- 32 • What symptoms did they present with?
- 33 • What signs did they have?
- 34 • What was the initial diagnosis? And why?
- 35 • Were any tests done?
- 36 • Did any external factors influence the decision for the initial diagnosis?
- 37 • When did they see you or another colleague again?
- 38 • If it was another colleague, what specialty did they work in?
- 39 • Did anything change with the signs/symptoms?
- 40 • What happened next?
- 41 • Do you know what the final diagnosis was?
- 42 • What were the reasons for the delay in the diagnosis?
- 43 • Why was it difficult to make an accurate diagnosis on first consultation?

44 **We want to establish if it is possible to determine a core group of features that can be used to help  
45 diagnose lower limb cellulitis**

46 Prompts:

- 47 • What symptoms are you asking about?

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- Of these symptoms, which do you think are more suggestive of cellulitis?
  - Are there any symptoms that make cellulitis less likely?
  - Are there other features in the history which make cellulitis more/less likely? (prompt – other conditions, previous history, drugs, family history )
  - What signs are you looking for?
  - Of these signs, which do you think are more suggestive of cellulitis?
  - Would you request any tests if it was available to you on the same day?
  - If so what tests would these be?
  - Are there any signs in a 'red leg' that would make cellulitis less likely as the diagnosis?
  - Are there any signs in a red leg which would make cellulitis more likely as the diagnosis?
  - How has your approach to diagnosing cellulitis changed after managing previous cases?
  - If the patient has had previous cellulitis, does this influence your diagnosis?
  - From your experience, what differential diagnoses do you think about?
  - How do you distinguish cellulitis from these differential diagnoses?
  - Specifically, how do you differentiate cellulitis from lymphoedema?
  - Specifically, how do you differentiate cellulitis from venous eczema?
  - Specifically, how do you differentiate cellulitis from infected venous eczema?
  - Specifically, how do you differentiate cellulitis from lymphodermatosclerosis?
  - Do you feel that a list of key diagnostic features of cellulitis would help when assessing patients?

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29 72 **We want your views on some aspects of diagnosis that patients with recurrent cellulitis and**  
30 73 **lymphoedema have discussed**

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- Patients felt that they were confident in making a self-diagnosis of cellulitis and valued greater trust in self-management at home with treatment. What are your thoughts on patients self-diagnosing?
  - Would a photograph with a proforma taken and filled in by the patient and sent to you be helpful in managing patients with recurrent cellulitis?
  - In the instance where you may not agree with the patients self-diagnosis of cellulitis, how would you manage the diagnosis?
  - Do you feel that any further training or resources should be set up to help improve our diagnosis of cellulitis? For example as specialist cellulitis clinic to refer patients to?
  - What are your thoughts on health care professionals having a guide such as checklist to help diagnosis?
  - Do you think patients should have this checklist? If so why or why not?



## Standards for Reporting Qualitative Research (SRQR)\*

<http://www.equator-network.org/reporting-guidelines/srqr/>

Page/line no(s).

### Title and abstract

<p><b>Title</b> - Concise description of the nature and topic of the study Identifying the study as qualitative or indicating the approach (e.g., ethnography, grounded theory) or data collection methods (e.g., interview, focus group) is recommended</p>	<p>Page 1/line 1-2</p>
<p><b>Abstract</b> - Summary of key elements of the study using the abstract format of the intended publication; typically includes background, purpose, methods, results, and conclusions</p>	<p>Page 2/lines 43-67</p>

### Introduction

<p><b>Problem formulation</b> - Description and significance of the problem/phenomenon studied; review of relevant theory and empirical work; problem statement</p>	<p>Page 4/ lines 91-101</p>
<p><b>Purpose or research question</b> - Purpose of the study and specific objectives or questions</p>	<p>Page 4/lines 100-101</p>

### Methods

<p><b>Qualitative approach and research paradigm</b> - Qualitative approach (e.g., ethnography, grounded theory, case study, phenomenology, narrative research) and guiding theory if appropriate; identifying the research paradigm (e.g., postpositivist, constructivist/ interpretivist) is also recommended; rationale**</p>	<p>Page 7/lines 164-169</p>
<p><b>Researcher characteristics and reflexivity</b> - Researchers' characteristics that may influence the research, including personal attributes, qualifications/experience, relationship with participants, assumptions, and/or presuppositions; potential or actual interaction between researchers' characteristics and the research questions, approach, methods, results, and/or transferability</p>	<p>Page 6/ lines 140-146</p>
<p><b>Context</b> - Setting/site and salient contextual factors; rationale**</p>	<p>Page 6/lines 147-150</p>
<p><b>Sampling strategy</b> - How and why research participants, documents, or events were selected; criteria for deciding when no further sampling was necessary (e.g., sampling saturation); rationale**</p>	<p>Pages 5-6/ lines 122-139</p>
<p><b>Ethical issues pertaining to human subjects</b> - Documentation of approval by an appropriate ethics review board and participant consent, or explanation for lack thereof; other confidentiality and data security issues</p>	<p>Page 5/ lines 112-116</p>
<p><b>Data collection methods</b> - Types of data collected; details of data collection procedures including (as appropriate) start and stop dates of data collection and analysis, iterative process, triangulation of sources/methods, and modification of procedures in response to evolving study findings; rationale**</p>	<p>Page 6-7/ lines 152-159</p>

1 2 3 4 5	<b>Data collection instruments and technologies</b> - Description of instruments (e.g., interview guides, questionnaires) and devices (e.g., audio recorders) used for data collection; if/how the instrument(s) changed over the course of the study	Pages 6-7/ lines 152-159
6 7 8 9	<b>Units of study</b> - Number and relevant characteristics of participants, documents, or events included in the study; level of participation (could be reported in results)	In the results, Page 8/lines 181-182 and Table 1
10 11 12 13	<b>Data processing</b> - Methods for processing data prior to and during analysis, including transcription, data entry, data management and security, verification of data integrity, data coding, and anonymization/de-identification of excerpts	Page 6/ lines 160-162
14 15 16 17	<b>Data analysis</b> - Process by which inferences, themes, etc., were identified and developed, including the researchers involved in data analysis; usually references a specific paradigm or approach; rationale**	Page 7/lines 163-175
18 19 20 21	<b>Techniques to enhance trustworthiness</b> - Techniques to enhance trustworthiness and credibility of data analysis (e.g., member checking, audit trail, triangulation); rationale**	Page 7/ lines 164-175

### Results/findings

22 23 24 25 26 27	<b>Synthesis and interpretation</b> - Main findings (e.g., interpretations, inferences, and themes); might include development of a theory or model, or integration with prior research or theory	Pages 8-21/ lines 180-384
28 29 30	<b>Links to empirical data</b> - Evidence (e.g., quotes, field notes, text excerpts, photographs) to substantiate analytic findings	Pages 8-21/ lines 180-384

### Discussion

31 32 33 34 35 36 37 38	<b>Integration with prior work, implications, transferability, and contribution(s) to the field</b> - Short summary of main findings; explanation of how findings and conclusions connect to, support, elaborate on, or challenge conclusions of earlier scholarship; discussion of scope of application/generalizability; identification of unique contribution(s) to scholarship in a discipline or field	Page 22/lines 407-429, Pages 24-25/454-482
39 40 41	<b>Limitations</b> - Trustworthiness and limitations of findings	Page 23/ lines 430-451

### Other

42 43 44 45 46	<b>Conflicts of interest</b> - Potential sources of influence or perceived influence on study conduct and conclusions; how these were managed	Page 25/line 495-496
47 48 49	<b>Funding</b> – Sources of funding and other support; role of funders in data collection, interpretation, and reporting	Page 1/ lines 22-23

\*The authors created the SRQR by searching the literature to identify guidelines, reporting standards, and critical appraisal criteria for qualitative research; reviewing the reference lists of retrieved sources; and contacting experts to gain feedback. The SRQR aims to improve the transparency of all aspects of qualitative research by providing clear standards for reporting qualitative research.

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\*\*The rationale should briefly discuss the justification for choosing that theory, approach, method, or technique rather than other options available, the assumptions and limitations implicit in those choices, and how those choices influence study conclusions and transferability. As appropriate, the rationale for several items might be discussed together.

**Reference:**

O'Brien BC, Harris IB, Beckman TJ, Reed DA, Cook DA. **Standards for reporting qualitative research: a synthesis of recommendations.** *Academic Medicine*, Vol. 89, No. 9 / Sept 2014  
DOI: 10.1097/ACM.0000000000000388

For peer review only

# BMJ Open

## An interview study to determine the experiences of cellulitis diagnosis amongst health care professionals in the UK.

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2019-034692.R3
Article Type:	Original research
Date Submitted by the Author:	30-Jul-2020
Complete List of Authors:	Patel, Mitesh; University of Nottingham, ; Lee, Siang Ing; University of Nottingham, Nottingham, UK, Division of Primary Care & National Institute for Health Research, School of Medicine, Levell, Nick; Norfolk and Norwich University Hospital NHS Foundation Trust, Dermatology Smart, Peter; University of Nottingham, Nottingham, UK Kai, Joe; University of Nottingham, Nottingham, UK Thomas, Kim; University of Nottingham, Centre of Evidence Based Dermatology Leighton, Paul; University of Nottingham, Centre of Evidence Based Dermatology
<b>Primary Subject Heading</b>:	Dermatology
Secondary Subject Heading:	Infectious diseases, Qualitative research
Keywords:	DERMATOLOGY, Adult dermatology < DERMATOLOGY, Infectious diseases & infestations < DERMATOLOGY, QUALITATIVE RESEARCH

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1 **Title:** An interview study to determine the experiences of cellulitis diagnosis amongst health  
2 **care professionals in the UK.**

3 **Running head:** Cellulitis diagnosis by health care professionals

4 **Word count:** 3994

5 **Table count:** 4

6 **Figure count:** 1

7 **Supplementary material:** 1

8 **Authors:** M Patel, <sup>1,2</sup> S I Lee, <sup>1</sup> NJ Levell, <sup>3</sup> P Smart, <sup>4</sup> J Kai, <sup>1</sup> KS Thomas, <sup>2</sup> P Leighton, <sup>2</sup>

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11 <sup>2</sup> Centre of Evidence Based Dermatology, University of Nottingham, Nottingham, UK

12 <sup>3</sup> Dermatology Department, Norfolk and Norwich University Hospital NHS Trust, UK

13 <sup>4</sup> Patient representative, Centre of Evidence Based Dermatology, University of Nottingham,  
14 Nottingham, UK

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16 **ORCID ID:** M Patel (0000-0003-3975-4689), S I Lee (0000-0002-2332-5452), NJ Levell (0000-  
17 0003-3393-8305), J Kai (0000-0001-9040-9384), KS Thomas (0000-0001-7785-7465), P  
18 Leighton (0000-0001-5208-0274),

19 **Corresponding author:** Mitesh Patel, Division of Primary Care, School of Medicine, University of  
20 Nottingham, Nottingham, UK, Email: mpatel59@doctors.org.uk

21  
22 **Funding sources:** This study was supported by the Scientific Foundation Board of the Royal  
23 College of General Practitioners (grant SFB 2018 – 31).

24  
25 **Study registration:** Centre of Evidence Based Dermatology website -  
26 [https://www.nottingham.ac.uk/research/groups/cebd/documents/researchdocs/protocol-](https://www.nottingham.ac.uk/research/groups/cebd/documents/researchdocs/protocol-diagnosing-lower-limb-cellulitis-health-care-professionals.pdf)  
27 [diagnosing-lower-limb-cellulitis-health-care-professionals.pdf](https://www.nottingham.ac.uk/research/groups/cebd/documents/researchdocs/protocol-diagnosing-lower-limb-cellulitis-health-care-professionals.pdf)

28  
29 **Data sharing:** No additional data available

## Abstract

**Objectives:** To explore health care professionals (HCPs) experiences and challenges in diagnosing suspected lower limb cellulitis.

**Setting:** UK nationwide.

**Participants:** 20 qualified HCPs, who had a minimum of two years clinical experience as a HCP in the national health service and had managed a clinical case of suspected cellulitis of the lower limb in the UK.

HCPs were recruited from departments of dermatology (including a specialist cellulitis clinic), general practice, tissue viability, lymphoedema services, general surgery, emergency care and acute medicine.

Purposive sampling was employed to ensure that participants included consultant doctors, trainee doctors and nurses across the specialties listed above. Participants were recruited through: national networks,

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3 54 HCPs who contributed to the cellulitis priority setting partnership (PSP), UK Dermatology Clinical Trials  
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6 55 Network, snowball sampling where participants helped recruit other participants, personal networks of the  
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13 57 **Primary and secondary outcomes:** Primary outcome was to describe the key clinical features which inform  
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16 58 the diagnosis of lower limb cellulitis. Secondary outcome was to explore the difficulties in making a  
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19 59 diagnosis of lower limb cellulitis.

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22 60 **Results:** The presentation of lower limb cellulitis changes as the episode runs its course. Therefore,  
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25 61 different specialties see clinical features at varying stages of cellulitis. Clinical experience is essential to  
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28 62 being confident in making a diagnosis, but even amongst experienced HCPs, there were differences in  
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31 63 the clinical rationale of diagnosis. A group of core clinical features were suggested, many of which  
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34 64 overlapped with alternative diagnoses. This emphasises how the diagnosis is challenging, with objective  
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37 65 aids and a greater understanding of the mimics of cellulitis required.

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40 66 **Conclusion:** Cellulitis is a complex diagnosis and has a variable clinical presentation at different stages.  
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43 67 Although cellulitis is a common diagnosis to make, HCPs need to be mindful of alternative diagnoses.

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47 68 **Keywords:** lower limb, cellulitis, diagnosis, health care professionals  
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54 70 **Article summary**



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3 71 Strengths and limitations of this study  
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- 7 72 • The research question was developed from research priorities in the cellulitis priority  
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10 73 setting partnership, involving patients.  
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14 74 • Participants were included nationally around the UK.  
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17 75 • Participants from various specialities that commonly diagnose cellulitis were recruited.  
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20 76 • Our recruitment strategy is most likely to have targeted health care professionals with an  
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23 77 interest in dermatology.  
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26 78 • The size and scope of the sample population is a limitation.  
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25 90 **Introduction**

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29 91 Cellulitis is a frequent presentation in both the community and secondary care, with 60% of  
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32 92 presentations affecting the lower limbs.<sup>1</sup> However, the diagnosis of cellulitis can be challenging,  
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35 93 with up to a third of suspected lower limb cellulitis cases being later diagnosed as other  
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38 94 diagnoses.<sup>2</sup> This results in avoidable hospital admissions and unnecessary antibiotic prescribing  
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41 95 <sup>3</sup> and is further compounded by the lack of validated diagnostic criteria or tools for cellulitis.<sup>4</sup>

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45 96 A UK cellulitis research priority setting partnership (PSP) determined that improving health care  
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48 97 professionals' (HCPs) diagnostic accuracy is a key priority for future cellulitis research.<sup>5</sup> An  
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51 98 interview study of people with recurrent cellulitis and lymphoedema suggested that patients  
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55 99 often experience difficulties in obtaining a speedy and accurate diagnosis. <sup>6</sup>

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3 100 The aims of this interview study were to explore the HCP experiences and challenges faced in  
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49 111 **Methods**  
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53 112 **Protocol registration and Ethics**  
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3 113 The final protocol was registered on the Centre of Evidence Based Dermatology (CEBD)  
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6 114 website (9 May 2019). Ethical approval was granted by the Health Research Authority and  
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9 115 Health and Care Research Wales (19/HRA/0485) (30 November 2018). Verbal and written  
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13 116 consent was obtained from each participant.  
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### 17 117 **Patient and public involvement**

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21 118 The research question was developed from research priorities in the cellulitis PSP, involving  
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24 119 patients. A patient representative helped design this study and is a co-author. On publication,  
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27 120 participants will be sent the final manuscript.  
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### 31 121 **Eligibility criteria**

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45 125 cellulitis of the lower limb in the UK. Two years' experience was the minimum requirement as  
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48 126 then HCP's will have gained adequate exposure to cellulitis cases. HCPs were recruited from  
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26 136 • Personal networks of the authors
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29 137 Potential participants were approached and recruited by email. Data collection and analysis  
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32 138 were undertaken concurrently and sampling ceased when thematic saturation had been  
33  
34  
35 139 achieved (i.e. new interviews generated no new insights).<sup>7</sup>

#### 38 140 **Researcher characteristics**

41  
42 141 Interviews were conducted by MP (male), and coded and analysed by MP and SIL (female)  
43  
44  
45 142 (both general practitioner (GP) trainees who had managed clinical cases of cellulitis previously).  
46  
47  
48 143 Both MP and SIL attended qualitative methodology training courses. The broader research  
49  
50  
51 144 group included experienced clinical-academics (JK (academic GP) and NL (clinical professor of  
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3 145 dermatology), a patient representative (PS) and senior qualitative experts (JK and PL). Three  
4  
5  
6 146 participants had clinical interactions with the interviewer in the past, but not regarding cellulitis.  
7  
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9

### 10 147 **Interview setting**

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13  
14 148 Each participant took part in a single, semi-structured, qualitative interview. Two interviews were  
15  
16  
17 149 face to face, with the remaining via telephone. Written consent was gained from participants,  
18  
19  
20  
21 150 with additional verbal consent gained before the interview. All participants received a £20  
22  
23  
24 151 reimbursement voucher or donated this fee to the British Skin Foundation charity.  
25  
26

### 27 152 **Data collection**

28  
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31 153 Prior to the interview, participants were asked to reflect upon their most recent experiences of  
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34 154 making a cellulitis diagnosis, focusing on the typical presentations, challenging cases and  
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37 155 differential diagnoses.  
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41  
42 156 A topic guide, informed by a prior systematic review and interview study,<sup>8</sup> was used to structure  
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44  
45 157 the interview (Supplementary material). However, participants were urged to propose and/or  
46  
47  
48 158 expand on topics which they felt were relevant to their experience of diagnosis. New topics were  
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50  
51 159 then added to the topic guide for subsequent interviews.  
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### 55 160 **Data processing**

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3 161 Interviews were audio-recorded and transcribed. Transcripts were checked (by MP) and data  
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5  
6 162 managed using QSR NVivo 12 software.  
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9

### 10 11 163 **Data analysis** 12

13  
14 164 Analysis was inductive, searching for themes in the data. A structured, systematic, multi-stage  
15  
16  
17 165 approach to thematic analysis was followed.<sup>9</sup> Coders immersed themselves in the data, by  
18  
19  
20  
21 166 reading the data set before coding. Data were coded manually by MP, with SIL also  
22  
23  
24 167 independently coding a third of the transcripts. A list of each code, with a brief description was  
25  
26  
27 168 then used to group the codes into theme-piles. Themes were defined and refined, with sub-  
28  
29  
30  
31 169 themes also developed.  
32

33  
34 170 Uncertainties in coding and thematic organisation were resolved in discussion with the other  
35  
36  
37 171 authors. Data collection and analysis was concurrent. The final codebook was agreed by all  
38  
39  
40  
41 172 authors and is presented in Figure 1. The interviewer kept a reflexive research diary, logging  
42  
43  
44 173 intuitive thoughts and immediate reflections after each interview. These reflections, as well as  
45  
46  
47 174 queries around data collection, handling and interpretation were then discussed at regular  
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51 175 research meetings.  
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## 180 Results

181 Twenty HCPs were interviewed (Table 1). The age range was 29-67 years; 15 were female; six  
 182 had <10 years of clinical experience, nine had 11-20 years and five had >20 years. Interviews  
 183 were conducted between 19 March and 11 June 2019, with a mean duration of 29 minutes.

184 **Table 1: Characteristics of the participants**

Participant	Ethnicity	Clinical role	Number of times they have diagnosed cellulitis	Time since they last diagnosed cellulitis
1	Asian British	GP	>50	One week ago
2	White British	Acute medicine/infectious disease consultant	>50	One week ago
3	White Irish	GP	>50	Three weeks ago
4	White British	Acute medicine consultant	>50	Last four weeks
5	White British	Acute medicine consultant	>50	One week ago



6	White British	Tissue viability nurse	10-50	Less than one week
7	White British	Lymphoedema specialist nurse	>50	One week ago
8	Asian British	Emergency medicine consultant	>50	Less than one week
9	Asian British	Dermatology consultant	10-50	Four weeks ago
10	White British	District nurse	>50	Last three months
11	Black	GP trainee	10-50	Less than one week
12	White British	GP locum	10-50	Two weeks ago
13	White British	GP out of hours	>50	Two weeks ago
14	White British	Dermatology specialist nurse	>50	Last three months
15	White British	Dermatology consultant	10-50	Last 12 months
16	Mixed	Surgical trainee	10-50	Last four weeks
17	White British	Community advanced nurse practitioner	>50	Less than one week
18	White British	Dermatology trainee	>50	Four weeks ago
19	White British	Emergency medicine consultant	>50	Last three months
20	White British	Dermatology consultant	>50	Less than one week

185

## 186 Main findings

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3 187 Four key themes were identified: 1) The patient presentation; 2) Challenges leading to  
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6 188 diagnostic uncertainty; 3) Strategies to improve diagnosis; 4) The need for an objective  
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9 189 diagnostic aid, with further classification into sub-themes. How the codes mapped onto the  
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13 190 overarching themes are shown in Table 2.  
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41 199 **Table 2: How the codes mapped onto themes**  
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Themes	Sub-themes	Codes
<b>The patient presentation</b>	The typical patient and risk factors	<ul style="list-style-type: none"> <li>• Typical cellulitis presentations</li> </ul>
		<ul style="list-style-type: none"> <li>• Factors that increase the likelihood of cellulitis diagnosis</li> </ul>
	Confidence in diagnosis	<ul style="list-style-type: none"> <li>• Most suitable HCP to diagnose cellulitis</li> <li>•</li> </ul>
		<ul style="list-style-type: none"> <li>• Experience guides diagnosis</li> </ul>
	Cases of misdiagnoses	<ul style="list-style-type: none"> <li>• Missed/delayed diagnosis of cellulitis (final diagnosis)</li> </ul>
		<ul style="list-style-type: none"> <li>• Missed/delayed diagnosis of cellulitis (initial diagnosis)</li> </ul>
Differential diagnoses	<ul style="list-style-type: none"> <li>• List of alternative diagnosis</li> </ul>	
<b>Challenges leading to diagnostic uncertainty</b>	Continuum of clinical features	<ul style="list-style-type: none"> <li>• Changes in clinical presentation</li> </ul>
	A subjective diagnosis	<ul style="list-style-type: none"> <li>• Reasons why cellulitis diagnosis is challenging</li> </ul>
	Community challenges	<ul style="list-style-type: none"> <li>• Seeing patients part way through assessment and management</li> </ul>
		<ul style="list-style-type: none"> <li>• Follow up of patients</li> </ul>
	The role of 'defensive' medicine	<ul style="list-style-type: none"> <li>• Sepsis as a concern</li> <li>• Medico legal issues as a factor</li> </ul>
		<ul style="list-style-type: none"> <li>• Fear of missing more serious differentials</li> </ul>
Patient specific factors	<ul style="list-style-type: none"> <li>• Other factors influencing diagnosis</li> </ul>	
<b>Strategies to improve diagnosis</b>	Using time as a guide	<ul style="list-style-type: none"> <li>• Time and safety netting approach</li> <li>•</li> </ul>
	Trial of treatment	<ul style="list-style-type: none"> <li>• Trial of treatment guides diagnosis</li> </ul>

		•
	Biochemical investigations	• Investigations to aid diagnosis
	Seeking advice	• Discussing diagnosis with colleagues
	Further education	• Suggestions on what may improve diagnosis
<b>The need for an objective diagnostic aid</b>	A diagnostic algorithm	• Views on diagnostic aids for HCP
	Indices for an algorithm	• Clinical features to include in diagnostic algorithm

## 200 **Diagnosis of cellulitis**

### 201 *The typical patient and risk factors*

202 In general practice, the typical patient described by participants included older adults with co-  
 203 morbidities; concerns of possible cellulitis cases were often raised by district nursing colleagues.  
 204 Emergency care and acute services described people who presented with features of systemic  
 205 compromise. Both infectious disease and general surgery services often managed intravenous  
 206 drug users who were at risk of deeper infection.

207 Factors that HCPs stated increased the likelihood of cellulitis were: features of systemic upset  
 208 including fever, malaise, rigors; co-existing injury or infection such as tinea, superficial  
 209 ulceration, previous history of cellulitis, previous history of dermatological conditions such as

1  
2  
3 210 eczema, diabetes, immunosuppressive medications and those with no fixed abode with social  
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6  
7 211 and health risks. Bilateral symptoms were commonly described by participants as a factor  
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9  
10 212 increasing the likelihood of chronic, systemic pathologies rather than cellulitis.  
11  
12

### 13 213 *Confidence in diagnosis*

14  
15  
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17  
18 214 One dermatologist explained how being more aware of the differential diagnoses made them  
19  
20  
21 215 more likely to accurately diagnose cellulitis, especially compared to junior colleagues. Generally,  
22  
23  
24 216 HCPs with more clinical experience felt more confident with diagnosis, as they appreciated the  
25  
26  
27 217 presentation with more observed cases '*I would say it is just experience [helping diagnosis], a*  
28  
29  
30 218 *lot of the juniors that come into A&E have not seen that many cellulitis [cases]* (P19, emergency  
31  
32  
33  
34 219 care consultant, 10 years clinical experience).  
35  
36  
37

38 220 A dermatology trainee felt seeing less cellulitis cases during their training compared to their  
39  
40  
41 221 senior colleagues historically, and therefore not getting as much exposure, hindered accurate  
42  
43  
44 222 diagnosis.  
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47 223

### 48 49 50 224 *Cases of misdiagnoses*

1  
2  
3 225 Trauma related skin changes was frequently an initial misdiagnosis in the emergency  
4  
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6  
7 226 department. When discussing cases of uncertainty, where cellulitis was the initial suspected  
8  
9  
10 227 diagnosis, one GP described a case of venous eczema which was managed with repeated  
11  
12  
13 228 antibiotics '*Generally anything that is red and hot on the legs is treated with antibiotics*' (P1, GP,  
14  
15  
16 229 >13 years clinical experience). Chronic rashes were frequently seen by dermatology and  
17  
18  
19 230 infectious disease discussed lymphoma cases initially referred as cellulitis '*We did see [patients]*  
20  
21  
22 231 *coming in with "Oh this must be a resistant cellulitis", have got a swollen limb that might be a*  
23  
24  
25 232 *little bit red and it turns out to be some horrible form of lymphoma*' (P2, infectious disease  
26  
27  
28 233 consultant, 25 years clinical experience).  
29  
30  
31  
32  
33 234 The importance of a correct diagnosis is key, as two participants discussed the possibility of  
34  
35  
36 235 prophylactic antibiotics for patients with recurrent cellulitis. A dermatology consultant explained  
37  
38  
39 236 how misdiagnosis can result in inappropriate and costly admissions to the ward.  
40  
41  
42

### 43 237 *Differential diagnoses*

44  
45  
46

47 238 A frequent diagnosis of uncertainty for primary and emergency care was deep vein thrombosis  
48  
49  
50 239 (DVT), as the clinical features of cellulitis can overlap '*One thing that is always a problem is leg*  
51  
52  
53 240 *swelling...it is difficult to ascertain between DVT and cellulitis*' (P8, emergency care consultant,  
54  
55  
56

20 years clinical experience). Common differential diagnoses discussed by participants, which they observed in their clinical practice, with discriminating features from cellulitis that they described, are shown in Table 3.

**Table 3:** Differential diagnoses of lower limb cellulitis discussed by participants

Differential diagnoses	Key differentiating factors from cellulitis
Chronic heart failure causing oedema	Chronic, bilateral, lack of mobility, breathless, cardiac history (P1,GP;P14,dermatology specialist nurse)
Venous eczema	Usually chronic with hemosiderin scaling, itching, crusting, likely bilateral, possibly eczema elsewhere on body, less well defined, (P3,GP;P15, dermatology consultant)
Thrombophlebitis	Tender, localised, hard, lumpy rash around an often-thickened vein (P3,GP;P5,acute medicine consultant;P12,GP locum)
Erythema nodosum	Multiple, discrete swellings (P13,GP out of hours)
Deep vein thrombosis	Pain is usually deep in calf rather than superficial, less sharply demarcated and less intense erythema, diffuse swelling of limb, can be young, can be intravenous drug users, high DVT wells score, fewer systemic features (P2,infectious disease consultant;P12,GP locum;P13,GP out of hours)

Lymphoedema	Chronic, bilateral, usually less painful, thickened warty skin in the long-term, normal inflammatory markers (P9,dermatology consultant;P18,dermatology trainee)
Allergic reaction to insect bites	Central puncture mark, itch, when acute, developing lichenified erythema when chronic (P2,infectious disease consultant)
Lipodermatosclerosis	Often bilateral, systemically well, tight non tender skin with inverted champagne bottle appearance (P4,acute medicine consultant; P20,dermatology consultant)
Necrotising fasciitis	Crepitus, rapidly spreading, septic, very tender (P5,acute medicine consultant; P16, surgical trainee)
Wound infection	Local to the wound, covers small area, yellow exudate, strong odour (P10,district nurse; P16,surgical trainee)
Baker's cyst	Unilateral popliteal swelling, suddenly more tender on rupture (P15,dermatology consultant)

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246

## 247 Challenges leading to diagnostic uncertainty

### 248 *The continuum of clinical features*



1  
2  
3 249 Participants described how the presentation of lower limb cellulitis changed as the episode ran  
4  
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6  
7 250 its course. This was influenced by when patients seek clinical review and meant that different  
8  
9  
10 251 specialties observed clinical features at varying stages of cellulitis.

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12  
13 252 In dermatology services, presentations were seen later in the episode. However, partial  
14  
15  
16 253 treatment and response did make the diagnosis challenging as the initial typical features of  
17  
18  
19 254 cellulitis may then vary. However, seeing patients later in the journey allowed dermatologists to  
20  
21  
22 255 appreciate the progression of clinical features '*I learnt to appreciate much more that [cellulitis] is*  
23  
24  
25 256 *coming up, it is happening and that it is fading away... When I was [junior], I was seeing*  
26  
27  
28 257 *[cellulitis] at the beginning and middle stages, trying to diagnose it, but in dermatology you're*  
29  
30  
31 258 *seeing it more at that other end of the spectrum...so I think there is a lot [to be] learnt about*  
32  
33  
34 259 *seeing that pattern developing and progressing and then resolving'* (P18, dermatology trainee,  
35  
36  
37 260 eight years clinical experience).

38  
39  
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41  
42 261 Importantly for dermatologists, other more serious pathologies such as a DVT had often been  
43  
44  
45 262 ruled out.

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47  
48  
49 263 *A subjective diagnosis*  
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3 264 One GP explained how there is no specific test that can aid diagnosis, thus subjective  
4  
5  
6 265 assessment can lead to different diagnoses *'I think the fact that there is no specific diagnostic*  
7  
8  
9 266 *test... and two different people can look at [possible cellulitis] and come up with two different*  
10  
11  
12 267 *answers'* (P1, GP, >13 years clinical experience). She added how this is further influenced by  
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14  
15 268 previous experiences, including how long and where HCPs have trained.  
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270

### 271 *Community challenges*

272 In the community, additional challenges for GPs were not being familiar with the patient's  
273 background history, seeing a patient for the first time, or taking over care part way through the  
274 patient journey. Working as a locum doctor with a lack of follow up available, often led to  
275 treatment when unsure of the diagnosis *'You've not met the patient before and sometimes*  
276 *you're not going to be able to follow them up so you probably are more likely to give antibiotics'*  
277 (P12, GP locum, seven years clinical experience). Limited resources to see patients, such as  
278 not being able to conduct an urgent home visit, also influenced diagnosis and subsequent  
279 management by GPs.

280 *The role of 'defensive' medicine*

281 HCPs in the community, emergency care and surgery were particularly wary of missing a more  
282 serious diagnosis, which needed to be ruled out first, such as DVT and necrotising fasciitis (NF)  
283 *'I think you would want to rule out DVT first because if you miss that then that is... a problem'*  
284 (P1, GP, >13 years clinical experience; P16, female, surgical trainee, five years clinical  
285 experience). Many HCPs also mentioned '*sepsis*' when discussing clinical features and  
286 diagnosis. This may be leading to an over diagnosis of cellulitis due to concerns of medico legal  
287 complaints of missing an infection which could then get worse *'We're all risk adverse aren't we?*  
288 *We would rather make sure we weren't sued because we had missed someone with an*  
289 *infection'* (P2, infectious disease consultant, 25 years clinical experience).

290 *Patient specific factors*

291 Participants found people with pigmented skin, lymphoedema and with nonspecific symptoms  
292 particularly difficult to diagnose in the acute setting *'One of these classical patients that comes*  
293 *in hasn't got a rash ... [or] the features of swelling, redness, rash and pain in the leg but they*  
294 *come in none specifically unwell ... I think those patients are much trickier [to diagnose cellulitis]'*  
295 (P5, acute medicine consultant, 16 years clinical experience). One nurse described another

1  
2  
3 296 diagnostic challenge was when a patient presents with chronic skin changes or a recent episode  
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6  
7 297 of cellulitis with continuing signs '*People with chronic red [legs], their legs are red most of the*  
8  
9  
10 298 *time... the skin takes so long to settle, so they could have had cellulitis four weeks ago and it is*  
11  
12  
13 299 *still red*' (P17, advanced nurse practitioner, 20 years clinical experience).

### 300 **Strategies used to reduce uncertainty**

#### 301 *Using time as a guide*

302 In cases where the HCP was not sure of the diagnosis, different strategies were employed.  
303 Using time to allow further clinical features to develop, with appropriate safety netting was a  
304 commonly used approach. This was easier when follow-up appointments were available in the  
305 community, but was also done in the acute setting '*So if they were well... then I would bring*  
306 *them back to clinic the next day or two*' (P4, acute medicine consultant, 17 years clinical  
307 experience). But follow-up in secondary care was difficult, often not done and can be a missed  
308 opportunity to learn from incorrect diagnoses previously.

#### 309 *Trial of treatment*

310 Some HCPs started antibiotics for a suspected cellulitis and reviewed the response to help  
311 provide the diagnosis retrospectively '*Cellulitis...was the easiest thing to try and treat so I think*  
312 *that definitely pushed [me] to try some antibiotics and see if this is an infection*' (P11, GP

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3 313 trainee, six years clinical experience). A major concern highlighted by one GP with this  
4  
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6  
7 314 approach was antibiotic resistance and side effects. However, overall, there was a common  
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9  
10 315 understanding in primary care why this approach was taken in some instances.  
11  
12

### 13 316 *Biochemical investigations*

14  
15  
16  
17 317 In primary care, one doctor described how blood tests and cultures were rarely done to  
18  
19  
20 318 diagnose cellulitis, as such patients would need to be seen in secondary care. Blood cultures  
21  
22  
23 319 were requested by the infectious disease physician if it was an atypical infection, but a  
24  
25  
26  
27 320 challenge described by one dermatology consultant was that organisms are not isolated in the  
28  
29  
30 321 majority of patients. Swabs were done for discharging wound infections, mainly by district  
31  
32  
33 322 nurses or prior to discussion with microbiology, when see by dermatologists.  
34  
35  
36

37 323 An emergency physician and surgical trainee explained how blood tests and imaging such as x-  
38  
39  
40 324 rays are important to check for osteomyelitis. The blood tests commonly requested by  
41  
42  
43 325 secondary care HCPs were white cell count (WCC) and C-reactive protein (CRP) for infection  
44  
45  
46 326 with one dermatologist stating how changes in blood test results were important when taking  
47  
48  
49 327 referrals for suspected cellulitis '*[With cellulitis]...you expect a) it is unilateral, b) you want some*  
50  
51  
52 328 *inflammatory markers which are raised, at least a reasonable WCC and CRP and if it is normal*  
53  
54  
55  
56

329 *it is not going to be cellulitis'* (P9, dermatology consultant, 10 years clinical experience).

330 However, one challenge with interpreting blood tests was in the group partially treated with  
331 antibiotics, who have improving blood tests but limited clinical response. A biomarker or point of  
332 care test for cellulitis were suggested as investigations to aid diagnosis by one dermatology  
333 consultant and one GP respectively.

### 334 *Seeking advice*

335 Another approach during uncertainty was to discuss with colleagues. In the community the  
336 nurse may ask the GP to review and vice versa. In hospital, specialists in infectious disease,  
337 dermatology, microbiology and general/plastic surgeons are most often contacted for review.

### 338 *Further education*

339 Many HCPs mentioned teaching sessions to improve diagnosis, both at the undergraduate and  
340 postgraduate level. One GP stated that real life clinical cases were felt to be important for  
341 teaching, rather than focusing on pictures '*It is all very well seeing pictures but pictures aren't*  
342 *that helpful sometimes, it is how it feels sometimes that makes a difference and actually seeing*  
343 *it in the flesh is very different to seeing even good quality pictures, so I do think that clinical*  
344 *exposure [is important]* (P13, GP, 20 years clinical experience).

1  
2  
3 345 A dermatology consultant suggested that a key area of education amongst HCPs was being  
4  
5  
6  
7 346 aware of differential diagnoses for frontline services '*It is not something people will have put a*  
8  
9  
10 347 *lot of thought into, the differentials, and I think the focus needs to be on teaching the frontline*  
11  
12  
13 348 *staff* (P15, dermatology consultant, 18 years clinical experience).

14  
15  
16  
17 349 One trainee who worked in a specialist cellulitis clinic found that seeing many cases helped  
18  
19  
20 350 improve her recognition of cellulitis.

## 21 22 23 24 351 **The need for an objective diagnostic aid**

### 25 26 27 352 *A diagnostic algorithm*

28  
29  
30  
31 353 Many participants mentioned developing a diagnostic algorithm, similar to the Wells score for  
32  
33  
34 354 DVT. A GP explained how this may also help GPs make a validated clinical decision when  
35  
36  
37 355 colleagues such as district nurses are suspecting cellulitis and the patient cannot be seen  
38  
39  
40 356 quickly. A dermatology nurse described how she often used checklists and how an algorithm  
41  
42  
43 357 would help HCP's not to miss any clinical features '*[A checklist] could help people that weren't*  
44  
45  
46 358 *experienced or confident enough...it just gives you something to think about like "oh I hadn't*  
47  
48  
49 359 *thought about the heat"*' (P14, dermatology nurse, nine years clinical experience).

1  
2  
3 360 One dermatology consultant suggested that a diagnostic checklist should be more of an  
4  
5  
6 361 educational tool to help rule out other differential diagnoses '*For a diagnostic checklist you*  
7  
8  
9  
10 362 *almost want it to be provided as an education tool with photographs and descriptions... so that*  
11  
12  
13 363 *people can put these differential diagnoses into their head* (P15, dermatology consultant, 18  
14  
15  
16 364 years clinical experience).

17  
18  
19  
20 365 A dermatology trainee felt that the indices of a checklist would have to reflect how cellulitis  
21  
22  
23 366 changes through the course of the episode. Other challenges described by participants,  
24  
25  
26 367 regarding developing an algorithm were the number of alternative diagnoses, with features that  
27  
28  
29  
30 368 often overlapped with cellulitis and vague initial features. Another concern highlighted by a  
31  
32  
33 369 dermatology consultant was that algorithms will miss patients who may present with atypical  
34  
35  
36 370 features '*Sometimes the trouble with guidelines, algorithms... you could probably cover 95% but*  
37  
38  
39 371 *does it mean that actually the atypical 5% then [do not] get diagnosed?* (P20, dermatology  
40  
41  
42 372 consultant, 42 years clinical experience).

### 43 44 45 46 373 *Indices for an algorithm*

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49  
50 374 The key clinical features HCPs suggested to include in a diagnostic algorithm for lower limb  
51  
52  
53 375 cellulitis were: unilateral, pain, erythema, warmth of limb, pyrexia, swelling, acute onset, trauma



376 to the limb, break in the skin, single area affected, clear demarcation, exudate, flu like malaise,  
 377 tracking rash, shiny, tenses skin, previous cellulitis, co-existing immunosuppression, co-existing  
 378 skin conditions, clinical observations for sepsis, negative Wells score and patient concern. No  
 379 HCP suggested blood tests were a priority in the algorithm, but a GP trainee suggested it could  
 380 be included in a modified algorithm in secondary care, similar to the CURB-65 score used for  
 381 pneumonia.

382

383 Additional quotes from participants are shown in Table 4.

384 **Table 4:** Additional quotes from participants, grouped into themes and subthemes

Themes	Subthemes	Participant quotes
The patient presentation	Confidence in diagnosis	<i>'I probably thought more presentations were [cellulitis] as a junior doctor... I probably didn't really recognise that sort of stretched skin appearance.. I think that has come along as part of just experience over the years, so I probably diagnosed more cellulitis inappropriately as a more junior doctor'</i> (P13, GP out of hours, 20 years clinical experience)
	Cases of misdiagnoses	<i>'One of the nurse practitioners had seen ankle swelling and the patient thought it... he played some cricket two or three days ago and after one or two days the swelling appeared and she thought that it was just a sprain but next day he represented, I saw him and it looked more like cellulitis because it was quite red, localised area... on close examination I could see a couple of scratches around the ankle so that was maybe the source of cellulitis spreading on the leg'</i> (P8, emergency care consultant, 20 years clinical experience)

		<i>'There are too many chronic rashes that get referred [to dermatology] as cellulitis'</i> (P18, dermatology trainee, eight years clinical experience)
<b>Challenges leading to diagnostic uncertainty</b>	<b>Continuum of clinical features</b>	<i>'Usually the patient is already admitted ... [the referring team] have tried [multiple antibiotics], but nothing is happening, "please can you come and tell us what is going on?"'</i> (P9, dermatology consultant, 10 years clinical experience)  <i>'There are varying ranges of erythema, from a little bit of light pinkness to rip roaring hot red, tender, well demarcated, unilateral; the classic sort of textbook stuff'</i> (P18, dermatology trainee, eight years clinical experience)  <i>'Virtually every patient that I see...they have had their d-dimer and their duplex done so [DVT] is usually a diagnosis that has been excluded'</i> (P20, dermatology consultant, 42 years clinical experience)
	<b>Community challenges</b>	<i>'If you know the patient and you know that they have recurrent cellulitis, someone had seen it like a district nurse and it is Friday afternoon and you can't get out [for a visit].. you would make a judgement call'</i> (P1, GP, >13 years clinical experience)
	<b>The role of 'defensive' medicine</b>	<i>'We're so much more aware of things like sepsis... looking at any kind of signs of infection'</i> (P10, district nurse, 25 years clinical experience)
<b>Strategies to improve diagnosis</b>	<b>Using time as a guide</b>	<i>'All you can really do is reassure the patient and say...I don't see any clear evidence of cellulitis but we will keep an eye on it.. you give safety net advice to the patients'</i> (P18, dermatology trainee, eight years clinical experience)
	<b>Trial of treatment</b>	<i>'[My concerns with this approach] are antibiotic resistance and side effects...especially in older groups...I would say probably that is not the best approach'</i> (P3, GP, 18 years clinical experience)
	<b>Biochemical investigations</b>	<i>'If I am thinking about doing blood tests...it is unlikely that I am going to continue managing them in the community'</i> (P11, GP trainee, six years clinical experience)

		<i>'I would never not diagnose somebody [with cellulitis] just because their inflammatory markers are normal (P5, acute medicine consultant, 16 years clinical experience)</i>
	<b>Further education</b>	<i>'You very quickly just get entrenched in...your preferences for diagnoses and it is often good to refresh' (P11, GP trainee, six years clinical experience)</i>  <i>'I only did two weeks [of dermatology] as a medical student... but certainly increasing dermatology teaching at an earlier stage would make a massive difference' (P13, GP, 20 years clinical experience).</i>  <i>'Pattern recognition and [seeing] variation in the progression of the rash [are important], thereby appreciating the 'life of rashes' (P18, dermatology trainee, eight years clinical experience).</i>
<b>The need for an objective diagnostic aid</b>	<b>A diagnostic algorithm</b>	<i>'I think it can be helpful to have those objective measures [of an algorithm], if it was accepted and validated as a reasonable measure of cellulitis, I think I would actually use that (P11, GP trainee, six years clinical experience).</i>  <i>'You would have to develop a criteria that can pick up the beginning, it is in the middle and it is resolving at the end (P18, dermatology trainee, eight years clinical experience).</i>  <i>'Because there is such a wide differential...how would you exclude all of those and also it can be quite nonspecific sometimes in the early stages' (P12, GP locum, 7 years clinical experience).</i>

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67 407 **Discussion**  
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11 408 **Summary**  
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15 409 This study found that the presentation of lower limb cellulitis changes as the episode  
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18 410 progresses, leading to variation in the clinical features, seen in different clinical settings. This  
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22 411 may be reflected in the range of typical differential diagnoses that specialities discussed and  
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25 412 has been described in literature.<sup>10</sup>  
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29 413 Clinical experience was described as an important factor in making a more accurate diagnosis.  
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32 414 Dermatologists have previously been suggested as the ideal HCP to diagnose cellulitis.<sup>11</sup>  
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35 415 However, the clinical reasoning behind a diagnosis were contradictory between some HCPs.  
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39 416 A core group of clinical features to diagnose cellulitis were suggested. But the challenge is that  
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42 417 these features can overlap with other pathologies, irrespective of how likely these are.<sup>12</sup> More  
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46 418 serious pathologies then need to be ruled out first, both for the safety of the patient and to avoid  
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49 419 medico-legal consequences.  
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3 420 Suggestions to improve the accuracy of diagnoses included developing a diagnostic algorithm  
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7 421 which could objectively help HCPs with different levels of experience.<sup>13</sup> The challenge with a  
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10 422 diagnostic algorithm is that it would need to incorporate the various stages of a cellulitis episode  
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13 423 and therefore various versions of an algorithm might be required.  
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17 424 Importantly, having a greater understanding of the alternative diagnoses is required, especially  
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20 425 when the features are vague, atypical or not responding to antibiotic treatment. Educating both  
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23 426 doctors and nurses, using real life clinical scenarios and a focus on differential diagnoses, was  
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26 427 also discussed and may be an initial feasible approach to improve diagnostic accuracy. A  
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29 428 visually based computerized diagnostic decision support system, focusing on differential  
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32 429 diagnoses, has been shown to improve the diagnostic accuracy of cellulitis.<sup>14</sup>  
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### 37 430 **Strengths and limitations**

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41 431 A key strength of this study that participants were included nationally around the UK, across  
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44 432 various specialities that commonly diagnose cellulitis, with both nurses and doctors of varying  
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47 433 clinical experience.

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51 434 Like similar studies, the size and scope of the sample population is a limitation of this work.  
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54 435 Whilst we argue that our findings are transferable to other settings, we acknowledge that those  
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3 436 interviewed were perhaps more interested and better informed about dermatology than many  
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7 437 HCPs. This was a function of our purposive sampling, and the likelihood that those interested in  
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10 438 cellulitis were more likely to consent to an interview. Furthermore, the participants in this study  
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13 439 were mainly female doctors. This may not be representative of the workforce in non-UK  
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16 440 countries; therefore the transferability of our findings may be limited.

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20 441 Some participants were unable to fully describe their clinical rationale behind diagnostic  
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23 442 decisions during the interview. This may be because they have developed an intuitive, pattern-  
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26 443 recognition, approach in decision-making with experience. Such heuristic diagnostic processes  
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30 444 in dermatology are well documented.<sup>15</sup>

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34 445 As the interviewer was a fellow clinician, interviewees may not have fully shared the details of  
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37 446 cases that were misdiagnosed or where diagnoses were delayed due to social desirability bias  
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40 447 or fear of litigation. Clinical researcher bias was unavoidable, as the interviewer had clinical  
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43 448 insight into cellulitis. However, non-clinicians within the broader authorship group were also  
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46 449 involved with coding and analysis of the interviews.

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50 450 Three participants were known to the interviewer, which can lead to response bias, however the  
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53 451 interviewer felt this also allowed an honest, open discussion.

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11 454 **Comparison with existing literature**

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15 455 To our knowledge, this is the first interview study undertaken with health care professionals,  
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18 456 discussing their experiences of cellulitis diagnosis. Our findings on the clinical features of  
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21 457 cellulitis, differential diagnoses and also the need to be aware of mimics have been described in  
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24 458 previous review articles.<sup>10</sup> A previous review also described cases of misdiagnosis and  
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27 459 emerging approaches to improve diagnoses,<sup>8,16</sup> which were echoed in this study. The  
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30 460 diagnostic challenges of infection in primary care, due to atypical presentations and lack of  
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33 461 diagnostic tests has previously been described.<sup>17</sup> Using treatments such as antibiotics as  
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36 462 diagnostic aids and discussing with colleagues when uncertain about a diagnosis are common  
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39 463 strategies.<sup>18,19</sup> Litigation and fear missing a diagnosis has also been well documented in  
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42 464 literature.<sup>20</sup>

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48 465 **Implications for research and practice**

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52 466 This study has highlighted that HCPs need to be aware that cellulitis can present with different  
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55 467 features at various stages of the acute episode and need to consider the cellulitis mimics. With



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3 468 a current shift in health care resulting in trained nurses now managing more acute  
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7 469 presentations,<sup>21</sup> upskilling nurses in cellulitis could be part of the solution.  
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10 470 Many HCPs felt confident in making an accurate diagnosis, often guided by experience and  
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14 471 intuition, but found it difficult to verbalise the key distinguishing features. This makes it difficult  
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17 472 for the clinical experience to be shared amongst other colleagues, especially less experienced  
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20 473 or junior HCPs. Acquiring this insight is important to improve diagnostic accuracy, which can  
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23 474 prevent avoidable antibiotic prescribing and hospital admissions. To overcome this, further  
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26 475 qualitative research is required to identify the clinical reasoning behind the expert process of  
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29 476 making a diagnosis, perhaps using clinical cases and pictures. This will form the basis of the  
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33 477 proposed solution of focused education and clinical features to be included in a diagnostic aid.  
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36 478 The challenge with further education for HCPs is that information needs to be accessible for  
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39 479 everyone, whilst information overload can lead to a reduction in the quality of decisions.<sup>22</sup>  
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43 480 Some indices and risk factors for a diagnostic algorithm have been identified in this study and  
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46 481 previous studies,<sup>23</sup> as well as key distinguishing features from differential diagnosis, but these  
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49 482 need validating with larger studies and an expert consensus setting exercise.  
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## 53 54 483 **Conclusion**

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3 484 This interview study has shown that cellulitis is a complex diagnosis. Not only does the core  
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7 485 features overlap with other diagnoses, the presentation of cellulitis changes as the episode  
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10 486 progresses. Although cellulitis is a common diagnosis to make, and whilst further research in  
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13 487 developing diagnostic aids needs to be undertaken, simply being aware of the cellulitis mimics  
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16 488 may help improve diagnostic accuracy.  
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31 492 this study. The views expressed in this paper are those of the authors and not necessarily those  
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34 493 of the National Health Service, the National Institute for Health Research or the Department of  
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## 41 495 **Competing interest**

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45 496 None declared  
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## 49 497 **Author contributions**

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53 498 **M Patel** was involved with the design of the study, collection and analysis of data, drafting the  
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55 499 manuscript and final approval of the manuscript.  
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4 500 **S I Lee** was involved with the design of the study, analysis of data, drafting the manuscript and  
5 501 final approval of the manuscript.  
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7 502 **NJ Levell** was involved with the design of the study, analysis of data, drafting the manuscript  
8 and final approval of the manuscript.  
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11 504 **P Smart** was involved with the design of the study, analysis of data, drafting the manuscript and  
12 505 final approval of the manuscript.  
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15 506 **J Kai** was involved with the design of the study, analysis of data, drafting the manuscript and  
16 507 final approval of the manuscript.  
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19 508 **KS Thomas** was involved with the design of the study, analysis of data, drafting the manuscript  
20 and final approval of the manuscript.  
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23 510 **P Leighton** was involved with the design of the study, analysis of data, drafting the manuscript  
24 and final approval of the manuscript.  
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**Figure 1: Standardised codebook used by two independent coders**

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**Supplementary Material**

**Topic guide used to structure the interview**



## Codes used

- Trial of treatment guides diagnosis
- Discussing diagnosis with colleagues
- Time and safety netting approach
- Patients who self-diagnose and treat
- Approach when HCPs do not agree with patient self-diagnosis
- Patients involved with diagnosis with the HCP
- Typical cellulitis presentations
- Clinical features of cellulitis
- Factors that decrease the likelihood of cellulitis diagnosis
- Factors that increase the likelihood of cellulitis diagnosis
- Investigations to aid diagnosis
- Missed/delayed diagnosis of cellulitis (final diagnosis)
- Missed/delayed diagnosis of cellulitis (initial diagnosis)
- Patient finds it difficult to accept it is not cellulitis
- Reasons why cellulitis diagnosis is challenging
- Suggestions on what may improve diagnosis
- Views on diagnostic aids for HCP
- Views on diagnostic aids for patients
- Views on how well HCP make diagnosis
- Experience guides diagnosis
- Seeing patients part way through assessment and management
- Differential diagnoses
- Sepsis as a concern
- Medico legal issues as a factor
- Follow up of patients
- Most suitable HCP to diagnose cellulitis
- Fear of missing more serious differentials
- Clinical features to include in diagnostic algorithm
- Other factors influencing diagnosis

1 **If the participant has a recent case of cellulitis that they can discuss:**

2 **Can you tell me about a case of cellulitis that you diagnosed?**

3 Prompts:

- 4 • What thoughts go through your head when you are considering a diagnosis of cellulitis?
- 5 • What symptoms do you ask about? Local? General?
- 6 • What signs do you look for? Local? General?
- 7 • Are there any specific signs/symptoms you rely on to help?
- 8 • Did you do any tests?
- 9 • Did you seek advice from anyone else?
- 10 • Were you concerned that this may not be cellulitis?
- 11 • If you were concerned, why?
- 12 • Was there anything challenging about this case?
- 13 • How did you address these challenges?
- 14 • How confident were you that this was cellulitis on a 1-10 scale when you first saw the patient?
- 15 • Did the patient discuss any self-diagnoses?
- 16 • Did any external factors such as time influence your decision?
- 17 • Did the patient come back to see you again?
- 18 • Would you change your approach if the same case presented again?
- 19 • Is this a typical case you see?
- 20 • What are the main differential diagnoses you see?

24 Repeat the above for a maximum two cases that the participants may have for the interview (repeat twice  
25 only if the participant has no delayed/incorrect cases below).

27 **If the participant has a case where the diagnosis was delayed or incorrect (can be initially either  
28 seen by same health care professional or a colleague, but preferably the same person)**

29 Prompts:

- 30 • Did you see the patient on initial presentation or was it a colleague?
- 31 • If it was another colleague, what specialty did they work in?
- 32 • What symptoms did they present with?
- 33 • What signs did they have?
- 34 • What was the initial diagnosis? And why?
- 35 • Were any tests done?
- 36 • Did any external factors influence the decision for the initial diagnosis?
- 37 • When did they see you or another colleague again?
- 38 • If it was another colleague, what specialty did they work in?
- 39 • Did anything change with the signs/symptoms?
- 40 • What happened next?
- 41 • Do you know what the final diagnosis was?
- 42 • What were the reasons for the delay in the diagnosis?
- 43 • Why was it difficult to make an accurate diagnosis on first consultation?

44 **We want to establish if it is possible to determine a core group of features that can be used to help  
45 diagnose lower limb cellulitis**

46 Prompts:

- 47 • What symptoms are you asking about?

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- Of these symptoms, which do you think are more suggestive of cellulitis?
  - Are there any symptoms that make cellulitis less likely?
  - Are there other features in the history which make cellulitis more/less likely? (prompt – other conditions, previous history, drugs, family history )
  - What signs are you looking for?
  - Of these signs, which do you think are more suggestive of cellulitis?
  - Would you request any tests if it was available to you on the same day?
  - If so what tests would these be?
  - Are there any signs in a 'red leg' that would make cellulitis less likely as the diagnosis?
  - Are there any signs in a red leg which would make cellulitis more likely as the diagnosis?
  - How has your approach to diagnosing cellulitis changed after managing previous cases?
  - If the patient has had previous cellulitis, does this influence your diagnosis?
  - From your experience, what differential diagnoses do you think about?
  - How do you distinguish cellulitis from these differential diagnoses?
  - Specifically, how do you differentiate cellulitis from lymphoedema?
  - Specifically, how do you differentiate cellulitis from venous eczema?
  - Specifically, how do you differentiate cellulitis from infected venous eczema?
  - Specifically, how do you differentiate cellulitis from lymphodermatosclerosis?
  - Do you feel that a list of key diagnostic features of cellulitis would help when assessing patients?

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29 72 **We want your views on some aspects of diagnosis that patients with recurrent cellulitis and**  
30 73 **lymphoedema have discussed**

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- Patients felt that they were confident in making a self-diagnosis of cellulitis and valued greater trust in self-management at home with treatment. What are your thoughts on patients self-diagnosing?
  - Would a photograph with a proforma taken and filled in by the patient and sent to you be helpful in managing patients with recurrent cellulitis?
  - In the instance where you may not agree with the patients self-diagnosis of cellulitis, how would you manage the diagnosis?
  - Do you feel that any further training or resources should be set up to help improve our diagnosis of cellulitis? For example as specialist cellulitis clinic to refer patients to?
  - What are your thoughts on health care professionals having a guide such as checklist to help diagnosis?
  - Do you think patients should have this checklist? If so why or why not?

## Standards for Reporting Qualitative Research (SRQR)\*

<http://www.equator-network.org/reporting-guidelines/srqr/>

Page/line no(s).

### Title and abstract

<p><b>Title</b> - Concise description of the nature and topic of the study Identifying the study as qualitative or indicating the approach (e.g., ethnography, grounded theory) or data collection methods (e.g., interview, focus group) is recommended</p>	<p>Page 1/line 1-2</p>
<p><b>Abstract</b> - Summary of key elements of the study using the abstract format of the intended publication; typically includes background, purpose, methods, results, and conclusions</p>	<p>Page 2/lines 43-67</p>

### Introduction

<p><b>Problem formulation</b> - Description and significance of the problem/phenomenon studied; review of relevant theory and empirical work; problem statement</p>	<p>Page 4/ lines 91-101</p>
<p><b>Purpose or research question</b> - Purpose of the study and specific objectives or questions</p>	<p>Page 4/lines 100-101</p>

### Methods

<p><b>Qualitative approach and research paradigm</b> - Qualitative approach (e.g., ethnography, grounded theory, case study, phenomenology, narrative research) and guiding theory if appropriate; identifying the research paradigm (e.g., postpositivist, constructivist/ interpretivist) is also recommended; rationale**</p>	<p>Page 7/lines 164-169</p>
<p><b>Researcher characteristics and reflexivity</b> - Researchers' characteristics that may influence the research, including personal attributes, qualifications/experience, relationship with participants, assumptions, and/or presuppositions; potential or actual interaction between researchers' characteristics and the research questions, approach, methods, results, and/or transferability</p>	<p>Page 6/ lines 140-146</p>
<p><b>Context</b> - Setting/site and salient contextual factors; rationale**</p>	<p>Page 6/lines 147-150</p>
<p><b>Sampling strategy</b> - How and why research participants, documents, or events were selected; criteria for deciding when no further sampling was necessary (e.g., sampling saturation); rationale**</p>	<p>Pages 5-6/ lines 122-139</p>
<p><b>Ethical issues pertaining to human subjects</b> - Documentation of approval by an appropriate ethics review board and participant consent, or explanation for lack thereof; other confidentiality and data security issues</p>	<p>Page 5/ lines 112-116</p>
<p><b>Data collection methods</b> - Types of data collected; details of data collection procedures including (as appropriate) start and stop dates of data collection and analysis, iterative process, triangulation of sources/methods, and modification of procedures in response to evolving study findings; rationale**</p>	<p>Page 6-7/ lines 152-159</p>

1 2 3 4 5	<b>Data collection instruments and technologies</b> - Description of instruments (e.g., interview guides, questionnaires) and devices (e.g., audio recorders) used for data collection; if/how the instrument(s) changed over the course of the study	Pages 6-7/ lines 152-159
6 7 8 9	<b>Units of study</b> - Number and relevant characteristics of participants, documents, or events included in the study; level of participation (could be reported in results)	In the results, Page 8/lines 181-182 and Table 1
10 11 12 13	<b>Data processing</b> - Methods for processing data prior to and during analysis, including transcription, data entry, data management and security, verification of data integrity, data coding, and anonymization/de-identification of excerpts	Page 6/ lines 160-162
14 15 16 17	<b>Data analysis</b> - Process by which inferences, themes, etc., were identified and developed, including the researchers involved in data analysis; usually references a specific paradigm or approach; rationale**	Page 7/lines 163-175
18 19 20 21	<b>Techniques to enhance trustworthiness</b> - Techniques to enhance trustworthiness and credibility of data analysis (e.g., member checking, audit trail, triangulation); rationale**	Page 7/ lines 164-175

### Results/findings

22 23 24 25 26 27	<b>Synthesis and interpretation</b> - Main findings (e.g., interpretations, inferences, and themes); might include development of a theory or model, or integration with prior research or theory	Pages 8-21/ lines 180-384
28 29 30	<b>Links to empirical data</b> - Evidence (e.g., quotes, field notes, text excerpts, photographs) to substantiate analytic findings	Pages 8-21/ lines 180-384

### Discussion

31 32 33 34 35 36 37 38	<b>Integration with prior work, implications, transferability, and contribution(s) to the field</b> - Short summary of main findings; explanation of how findings and conclusions connect to, support, elaborate on, or challenge conclusions of earlier scholarship; discussion of scope of application/generalizability; identification of unique contribution(s) to scholarship in a discipline or field	Page 22/lines 408-429, Pages 24-25/454-482
39 40 41	<b>Limitations</b> - Trustworthiness and limitations of findings	Page 23/ lines 430-451

### Other

42 43 44 45 46	<b>Conflicts of interest</b> - Potential sources of influence or perceived influence on study conduct and conclusions; how these were managed	Page 25/line 495-496
47 48 49	<b>Funding</b> – Sources of funding and other support; role of funders in data collection, interpretation, and reporting	Page 1/ lines 22-23

\*The authors created the SRQR by searching the literature to identify guidelines, reporting standards, and critical appraisal criteria for qualitative research; reviewing the reference lists of retrieved sources; and contacting experts to gain feedback. The SRQR aims to improve the transparency of all aspects of qualitative research by providing clear standards for reporting qualitative research.

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\*\*The rationale should briefly discuss the justification for choosing that theory, approach, method, or technique rather than other options available, the assumptions and limitations implicit in those choices, and how those choices influence study conclusions and transferability. As appropriate, the rationale for several items might be discussed together.

**Reference:**

O'Brien BC, Harris IB, Beckman TJ, Reed DA, Cook DA. **Standards for reporting qualitative research: a synthesis of recommendations.** *Academic Medicine*, Vol. 89, No. 9 / Sept 2014  
DOI: 10.1097/ACM.0000000000000388

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